American Hospital Association™
Advancing Health in America

Regulatory Advisory

November 18, 2022

Medicare Physician Fee Schedule Final Rule for CY 2023

The Centers for Medicare & Medicaid Services (CMS) Nov. 1 issued its physician fee schedule (PFS) final rule for calendar year (CY) 2023. The rule includes updates to physician payment and the Medicare Shared Savings Program (MSSP), as well as the Quality Payment Program (QPP) created by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015.

KEY HIGHLIGHTS

The final rule:

- Reduces the physician fee schedule conversion factor to $33.06 in CY 2023, as compared to $34.61 in CY 2022, which reflects: the expiration of the temporary 3% statutory payment increase; a 0.0% conversion factor update, as required by law; and a budget-neutrality adjustment
- Updates the Medicare Economic Index weights for CY 2023, although the revised weights were not used in CY 2023 rate setting
- Delays 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
- Adds several temporary telehealth codes to be available until the end of 2023 on a Category 3 basis, extends certain telehealth flexibilities through 151 days after the COVID-19 public health emergency expires in accordance with the Consolidated Appropriations Act and updates the originating site fee
- Provides advance shared savings payments to "low-revenue" Accountable Care Organizations that are both new to the Medicare Shared Savings Program and serve underserved populations, as well as increased flexibility for these ACOs to share in savings.
- Provides ACOs a more gradual glide path to two-sided risk.
- Modifies the ACO benchmarking methodology to help ensure that ACOs do not have to compete against their own best performance.
- Modifies MSSP quality scoring by adopting a sliding scale for shared-savings eligibility and adding a new health equity adjustment.
- Adds five new Merit-based Incentive Payment System Value Pathways (MVPs) for CY 2023.
- Increases the quality data completeness threshold to 75% and revises Promoting Interoperability objectives and measures.

AHA TAKE

The AHA is concerned with CMS' payment update, which reduces CY 2023 payments from their CY 2022 levels by almost 4.5%, and, as a result, may 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), increased inflation, rising staffing costs and increased costs for non-labor supply categories due to national shortages.

However, we are pleased that CMS is delaying 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.

Additionally, the rule adds many telehealth services for continued coverage through 2023 and extends for 151 days after the end of the COVID-19 PHE certain additional flexibilities. That said, we are concerned about the "telehealth cliff" that may result after the COVID-19 PHE expires, in which reductions in access and services would potentially be created. The AHA continues to encourage CMS to work with Congress on the permanent adoption of telehealth waiver provisions, such as eliminating the originating and geographic site restrictions for all telehealth services and expanding telehealth eligibility to certain practitioners.

We are encouraged by the modifications made in the CY 2023 final rule on the MSSP and Quality Payment Programs, which reflect many priorities on which we have worked with CMS. For the MSSP, for example, the final rule modifies the manner in which ACOs' benchmarks are calculated to help sustain long-term participation and reduce costs. It also provides increased flexibility for certain smaller ACOs to share in savings. We continue to encourage CMS to adopt policies which support flexible implementation and widespread adoption of value-based and alternative payment models.

WHAT YOU CAN DO

- **Register** to participate in AHA's Nov. 30 members-only webinar at 12:30 p.m. ET to discuss the regulation.
- **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 payment and quality changes on your Medicare revenue and operations.

FURTHER QUESTIONS

For additional questions, contact Jennifer Holloman, AHA's senior associate director for physician and alternative payment, at 202-626-2320 or jholloman@aha.org, or Akin Demehin, AHA's director for quality policy, at 202-626-2365 or ademehin@aha.org.

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CONVERSION FACTOR UPDATE

The payment update codified 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. **CMS finalized a cut to the conversion factor in CY 2023 to $33.06, 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

Changes to Medicare Telehealth Services List. 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. "Category 3" describes services added during the COVID-19 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 the 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 COVID-19 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 COVID-19 PHE, but not on a Category 1, 2, or 3 basis, the agency will maintain these services on the list for 151 days following the end of the COVID-19 PHE, as required by the Consolidated Appropriations Act, 2022 (CAA, 2022).

- Category 1. CMS adopted several codes brought forward for comment in the proposed rule. In all, five codes were added to Category 1 on a permanent basis, including prolonged service Healthcare Common Procedure Coding System (HCPCS) codes and chronic pain management codes.
- Category 3. CMS added 54 codes to the Category 3 designation including audiology services, certain therapy services, neurostimulator codes and emotional/behavior assessment services. These will be temporarily approved through CY 2023 to provide more time to evaluate efficacy and appropriateness for adoption on a permanent basis.

Services to be Removed from the Medicare Telehealth Services List after 151 Days Following End of the COVID-19 PHE. All other services that were temporarily added to the Medicare telehealth services list on an interim basis during the COVID-19 PHE and were not added to the list on a Category 1,2, or 3 basis will not remain on the list after the end of the COVID-19 PHE and 151 day extension. This includes certain codes that are temporarily in use for the state of emergency, but were not approved for Category 1,2, or 3 designations, including telephone E/M codes (except for behavioral health), GI Tract Imaging, and Continuous Glucose Monitoring. CMS reinforced that telehealth services should be services that are substitutes for in-person face to face visits.

Statutory Telehealth Flexibilities. Under the CAA 2022, CMS also include extends the following policies for 151 days after the COVID-19 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 Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) using the methodology established during the COVID-19 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 COVID-19 PHE. CMS stated that additional instructions and subregulatory guidance will be provided soon.

Use of Modifiers for Medicare Telehealth Services Following the End of the COVID-19 PHE. The final rule updates some of the telehealth coding guidance from the proposed rule. Prior to 2017, interactive audio-visual telehealth services were denoted using a "GT" modifier. In CY 2017, CMS updated guidance through the creation of a new place of service code "02" for telehealth, which was paid the facility payment rate. With the COVID-19 pandemic, practices shifted a significant portion of workload to virtual encounters which would have previously been in person, and relative resource costs were determined to not significantly differ between in person and virtual services. As such, in CY 2020, CMS finalized on an interim basis the use of modifier "95" for the PHE and to report the Place of Service where the service would have occurred. This ensured payment at the same rate that would have been paid if the services were furnished in-person.

CMS finalized updates to telehealth modifier guidance with modifications. Specifically,

- Providers will continue to bill telehealth services using a "95" modifier, along with the Place of Service code corresponding to where the service

would have been administered in-person *through the end of CY 2023 or end of the year in which the COVID-19 PHE ends*. CMS will maintain payment at the Place of Service had the service been in person, which will enable continued payment at the non-facility rate through the end of CY 2023 or end of the year in which the COVID-19 PHE ends. This was a change from the proposed rule, which had proposed transition back to the facility payment rate on the 152nd day after the PHE has expired, and use of Place of Service "10" for telehealth services described as taking place in the beneficiary's home and Place of Service "02" for those telehealth services not provided in a patient's home. In response to commenters concerns about payment stability immediately following expiration of the PHE, CMS reiterated and finalized that they will continue to maintain payment at the Place of Service had the service been delivered in person and will continue non-facility-based rates through the end of CY 2023 or end of the CY in which the PHE ends.

- All providers, including RHCs, FQHCs, and Opioid Treatment Programs (OTPs) *must* append Medicare modifier "FQ" for allowable audio-only services furnished in those settings.
- Beginning in January 2023, CPT modifier "93" *can* be added to claim lines for services furnished through audio-only technologies as appropriate. All providers, including RHCs, FQHCs and OTPs, *must* use modifier "93" when billing for eligible mental health services furnished via audio-only telecommunications technology. Providers can use either "FQ" or "93" modifiers or both where appropriate since they are identical in meaning.
- Supervising practitioners will continue to use "FR" modifier as appropriate for encounters where they provided direct supervision for a service using virtual presence via real-time, audio-visual telecommunications technology.

Expiration of COVID-19 PHE Flexibilities for Direct Supervision Requirements. During the COVID-19 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 COVID-19 PHE ends *or* Dec. 31, 2021, whichever is later. As such, CMS stated that it expects to continue to permit direct supervision through virtual presence through at least the end of CY 2023. CMS will continue to collect and consider comments for future rulemaking on whether to make this provision permanent.

Originating Site Facility Fee Update. CMS updated the originating site facility fee for CY 2023 from $27.59 to $28.64. This adjustment reflects the increase in MEI of 3.8%.

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 nonphysician practitioners (NPPs), CMS has addressed situations when physicians can bill for split visits. CMS says that 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. Medicare will pay only 85% of the fee schedule rate if the physician does not perform a substantive part of the split visit and the NPP bills for it.

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. Under this policy, 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, in the rule, CMS finalized its proposal to delay implementation of this policy for one year, until Jan. 1, 2024. Thus, for 2023, the substantive portion continues to be defined as either: one of the three key components of a visit, or more than half of the total time.

NEW CARE MANAGEMENT CODES FOR CHRONIC PAIN MANAGEMENT (CPM) AND GENERAL BEHAVIORAL HEALTH INTEGRATION (GBHI)

Chronic Pain Management (CPM) Bundles. CMS finalized its proposal 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 establishes 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 created two new HCPCS G-codes. G3002 covers services in a monthly bundle, including:

- Diagnosis
- Assessment and monitoring
- Administration of a validated pain rating scale or tool
- The development, implementation, revision and/or 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, e.g. physical therapy and occupational therapy, complementary and integrative approaches, and community-based care

CMS finalized the requirement that the first time G3002 is billed, the practitioner must see the beneficiary in-person. Follow-up or subsequent visits may be non-face-to-face; CMS is not limiting the place of service for these visits, and any of the components included in the codes may be furnished via telehealth as clinically appropriate. In the final rule, CMS clarifies that the beneficiary need not have an established history or diagnosis of chronic pain at the first visit; rather, the clinician who uses G3002 must establish or confirm the diagnosis when the beneficiary first presents for care. CMS will require that the beneficiary's verbal consent to receive CPM services at the initiating visit be documented in the beneficiary's medical record.

The add-on code, G3003, covers each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional. In the final rule, CMS did not finalize its proposal to limit billing of G3003 to three times per month; instead, CMS will allow providers to bill this code an unlimited number of times, as medically necessary, per month after G3002 has been billed.

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 will permit one additional billing by another practitioner after HCPCS code G3002 has already been billed in the calendar month. In addition, CMS will 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 will not allow these services to be billed on the same date of service as CPT codes 99202-99215 (office/outpatient visits new).

CMS will 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 G3002. CMS will value G3003 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 G3003 covers only an additional 15 minutes.

New Coding and Payment for General Behavioral Health Integration (BHI) Billed by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs). CMS finalized its proposal 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 created HCPCS code G0323. 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 will be allowed under general supervision. CMS values 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 are only be able to bill for services they furnish directly and personally. G0323 can 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 will allow a psychiatric diagnostic evaluation (CPT code 90791) to serve as the initiating visit for BHI.

AMENDING DIRECT SUPERVISION REQUIREMENT FOR "INCIDENT TO" BEHAVIORAL HEALTH SERVICES

Currently, CMS does not pay separately for professional services of auxiliary personnel, such as licensed professional counselors (LPCs) and licensed marriage and family therapists (LMFTs). Payment for these services can only be made under the PFS indirectly when auxiliary personnel perform 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 auxiliary personnel including (but not limited to) LPCs and LMFTs, CMS will allow auxiliary personnel to furnish behavioral health services under the *general* supervision of a physician or NPP when these services are provided incident to the services of a physician or NPP. This provision does not change the existing definition, scope of practice or requirements governing auxiliary personnel, nor does it change the definition of "incident to" services.

CHANGE IN PROCEDURE STATUS FOR FAMILY PSYCHOTHERAPY

Beginning Jan. 1, 2023, CMS will remove the restricted status indicator from the CPT codes that describe family psychotherapy and instead assign the codes 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 may result in less scrutiny (or the automatic application of *restrictions*) for these services by MACs.

PAYMENT FOR VACCINE ADMINISTRATIVE SERVICES

CMS finalized its proposal to annually update the payment amount for the administration of Part B preventive vaccines (HCPCS codes G0008-G0010) based upon the increase in the MEI. The MEI update for 2023 is 3.8%. CMS also finalized its proposal to adjust this payment amount geographically using the geographic adjustment factor (GAF). The agency also updated the $35.30 add-on payment for COVID-19 vaccine administration in beneficiaries’ homes by the MEI; the amount for 2023 is $36.85 and will be adjusted for geographic cost differences using the relevant GAF.

In addition, CMS finalized the update to the $40 payment amount for general COVID-19 vaccine administration using the MEI, as long as the Emergency Use Authorization (EUA) declaration is still in place. For 2023, payment for general COVID-19 vaccine administration will be $41.52. For the calendar year after the end of the COVID-19 PHE, the payment rates for COVID-19 vaccine administration will be adjusted in accordance with the payment rates for other Part B preventive vaccines. For the sake of example, if the COVID-19 PHE had ended in December 2022, COVID-19 vaccine administration payment would have dropped from $41.52 to $31.14 for 2023 (since that will be the rate for Part B Influenza, Pneumococcal, Hepatitis B vaccine administration).

EXPANSION OF COVERAGE FOR COLORECTAL CANCER SCREENING AND REDUCING BARRIERS

In the final rule, CMS expanded colorectal cancer screening coverage and payment limitations of certain screening tests to begin at age 45, instead of 50, in accordance with revised clinical standards. Coverage was also expanded to include follow-on screening colonoscopy after a Medicare-covered stool sample returns a positive result.

REVISING THE MEI

CMS rebased and revised the MEI based on a methodology that uses publicly available data sources for 2017 input costs that represent all types of physician practice ownership. Historically, the MEI was based on data representing only self-employed physicians. The agency did not apply the new weights to its payment methodology for ratesetting or to the GPCIs, so the payment impact will not occur this year. That said, once these new weights are used for payment, it will not change the overall spending on

services, but will impact distribution of payments across specialties and geographies in future rulemaking.

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.

Component	Final MEI (Final 2017 based)	Proposed MEI (Proposed 2017 based)	Current MEI (2006 based)
Physician Work	47.5%	47.3%	50.9%
Practice Expense	51.2%	51.3%	44.8%
Malpractice	1.3%	1.4%	4.3%

The percent change from the 2006-based MEI to the 2017 based MEI for CY 2023 is 3.8% based on historical data through the second quarter of 2022. Thus, CMS finalized an update factor of 3.8% for 2023, based on the most recent data available.

RURAL HEALTH CLINICS AND FEDERALLY QUALIFIED HEALTH CENTERS

Provider-Based RHC Payment-Limit Per-Visit. Under the Consolidated Appropriations Act of 2021, beginning April 1, 2021, a provider-based RHC is subject to a limit on its all-inclusive-rate (AIR).

The CY 2022 final rule finalized that if the RHC was already subject to a per-visit limit in 2020, its 2021 AIR limit would be the higher of its base year limit (its 2020 AIR limit) increased by the percentage increase in 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 would be the higher of its per visit payment amount for 2021 (its 2021 reasonable cost 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 CY 2023 final rule, CMS clarified the timing of cost reports to determine payment limits for provider-based RHCs, since the CY 2022 final rule did not address the requirement for cost reports to span a full 12-month period. For provider-based RHCs subject to a per-visit limit in 2020, the agency will 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 will 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 will 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 2021, the agency will 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

Effective Jan. 1, 2023, 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 (excluding radiopharmaceutical or imaging agents, drugs requiring filtration and new drugs). The refund amount is the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10% of total charges for the drug in a calendar quarter.

The rule includes policies to implement these provisions, including a policy 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 (described by HCPCS codes assigned status indicator “K” or “G”) or ASC payment system (described by HCPCS codes assigned payment indicator “K2”).

Specifically, CMS establishes a policy that, starting Jan. 1, 2023, for the purpose of calculating the refund amount during a relevant quarter, the JW modifier must 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 that were discarded. Further, beginning no later than July 1, 2023, CMS also will require HOPDs and ASCs to use a separate 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. The agency will begin claims edits for both the JW and JZ modifier beginning Oct. 1, 2023. Provider audits of Part B medication claims will be conducted periodically to determine whether the JW modifier, JZ modifier, and discarded drug amounts are billed appropriately, consistent with CMS’ 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 Access to Medicare Act (PAMA), CMS finalized 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 finalized various laboratory specimen collection fee policies with certain modifications and will also make updates to the Medicare Claims Processing Manual. Notably, after review of comments, CMS adjusted nominal specimen collection fees to account for inflation. Moving forward, CMS will adjust the nominal specimen collection fee based on inflation as measured by the CPI-U. The final rule:

- Updates the collection fee from $3 to $8.57 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)
- Updates the collection fee from $5 to $10.57 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
- Finalizes that the $10.57 fee for specimen collection will 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
- Clarifies that the specimen collection fee will only be paid for blood collected through venipuncture and urine through catheterization. The specimen collection fee will not be payable for any other specimen types, for example, a throat culture or a routine capillary puncture for clotting or bleeding time
- Clarifies that for the specimen collection fee to be paid, it must be drawn by a "trained technician"

Laboratory Specimen Collection Travel Allowance. CMS finalized modifications and clarifications to the Medicare CLFS specimen collection travel allowance policies. Two codes will be used to bill for travel allowance: 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. Historically, guidance for parameters like requirements for tracking mileage have been burdensome and components like proration methodology have been unclear.

For 2023, CMS codifies that the travel allowance will only be applicable where a specimen collection fee is also payable. Part B will cover the allowance when a laboratory technician draws a specimen only from a nursing home or homebound patient.

Additionally, CMS updated proposed provisions to include parameters that:
- only one travel allowance payment can be made based on the beneficiary's location and only when the collection is necessary for performance of the test;
- prorated travel allowances will only be applicable for Medicare beneficiaries;
- the flat rate methodology will continue to be used for trips less than or equal to 20 miles, but only for trips with one location where specimen(s) are collected;
- and the per-mile methodology will continue to be used for trips greater than 20 miles to and from one location for specimen collection or when the trained technician travels to more than one location for collection. Fees will be divided by the number of beneficiaries that a sample was derived from not the number of specimens that were collected.

Finally, CMS finalized policies related to the per-mile methodology. Notably, the start point and end point to calculate mileage will be the laboratory where the specimens are delivered for testing. Per-mile travel allowance will equal the sum of standard mileage

rate and travel technician mileage rate, multiplied by the number of eligible traveled miles. The standard mileage rate will be based on IRS's standard mileage rates and the travel technician mileage rate will be based on Bureau of Labor Statistics wage rates for phlebotomists.

Updates to the travel allowance will be made in subregulatory guidance.

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

CMS finalized 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. CMS will revise 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 will 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 will result in a payment amount of $39.37.

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 will 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 will 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 Drug Enforcement Agency.

Use of Telecommunications for Initiation of Treatment with Buprenorphine. CMS will 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 COVID-19 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 provision, CMS will allow periodic assessments to continue to be furnished using audio-only communication technology through the end of 2023 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 on Jan. 1, 2023, will begin initial EPCS compliance actions by issuing non-compliance letters.

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

MEDICARE SHARED SAVINGS PROGRAM (MSSP)

CMS made 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 finalized its proposals related to AIPs for certain ACOs. Specifically, eligibility criteria were updated to support ACOs treating underserved populations in covering upfront expenditures. In order to qualify, the ACO:

- cannot be a renewing ACO or re-entering ACO;
- must have 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);
- must be eligible to participate in the MSSP;
- must be inexperienced with performance-based risk Medicare ACO initiatives; and
- must be designated a low-revenue ACO (defined as the ACO's Medicare Parts A and B fee-for-service (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. The quarterly AIPs will 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 (if the beneficiary is not enrolled in LIS or dual eligible).

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

- AIPs will 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, the remaining balance would be carried over to subsequent PY(s);
- CMS will 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.

CMS also finalized that ACOs must use these payments to:

- improve health care provider infrastructure (e.g. investment in certified electronic health record technologies, telemonitoring, physical accessibility improvements, etc.)
- increase staffing (e.g. hiring case managers to screen for social determinants, hiring community health workers to deliver culturally tailored services, hiring a health equity officer, etc.), or
- provide accountable care for underserved beneficiaries, which may include addressing social needs (e.g. securing transportation services, implementing systems to provide and track patient referrals to available community-based

social services that address social needs, developing housing related services, etc.)

The final rule outlined that ACOs must submit spend plans as part of their application to describe how funds will be used to build care coordination capabilities, address specific health disparities and meet other criteria, as well as identifying the goods and services that will be purchased and their corresponding costs. Since these are advance shared savings, they are not payment or reimbursement for items or services. AIPs may not be used for any expense other than an allowable use under § 425.630(e)(1), and in the case of an ACO participating in Level E of the BASIC track, AIPs may not be used for the repayment of shared losses by ACOs participating in Level E of the BASIC track. Examples of prohibited used include (but are not limited to) parent company profit, provision of medical services covered by Medicare, or items unrelated to ACO operations that improve quality and efficiency of services furnished to beneficiaries. ACOs will also need to establish a separate designated account for deposit and expenditure of AIPs and will need to attest in the application that a separate account has been established for the deposit and expenditure of AIPs. CMS finalized that the initial application cycle to apply for advance investment payments will occur during CY 2023 for a Jan. 1, 2024, start date.

Transition to Performance-based Risk. In response to ongoing feedback from AHA and other stakeholders that the MSSP requires too much risk too soon, CMS finalized more-gradual transitions for certain ACOs in its final rule.

First, CMS modified the definition of "experience with performance-based risk Medicare ACO initiatives." Specifically, it will consider only Levels C through E of the BASIC track as "experience," not the one-sided Levels A and B. The agency will monitor status and will 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, will be able to elect to remain there for the remainder of their agreement period. ACOs beginning agreement periods on Jan. 1, 2024 will 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; and
- the ACO is inexperienced with performance-based risk Medicare ACO initiatives.

These ACOs will 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 finalized the proposal 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, will be permitted to complete the remainder of its current PY in a one-sided model of the BASIC track, but will be ineligible to continue participation in the one-sided model after the end of that PY. Instead, it will 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 will 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 codified changes designed to improve the calculation of ACO benchmarks. Modifications 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 will:

- 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 the final rule, CMS finalized its proposal to incorporate the Accountable Care Prospective Trend (ACPT), which is a variant of the United States Per Capita Cost (USPCC), 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. CMS did so in order to 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 also finalized the proposal to incorporate an adjustment for prior savings that will 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. This will 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 will 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 will also use a prior savings adjustment to offset negative regional adjustments for ACOs that are higher spending compared to their regional service area.

Negative Regional Adjustment. CMS finalized 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. First, it will lower 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. Additionally, after the cap is applied to the regional adjustment, the negative regional adjustment amount will gradually decrease as an ACO's proportion of dual eligible Medicare and Medicaid beneficiaries increases or its weighted average prospective risk score increases using an off.

CMS did review feedback on excluding an ACO's own assigned beneficiaries from the population used in regional expenditure calculations. However, the agency is concerned that this would incentivize providers to pick healthier patients without recalculating the regional adjustment, and recalculating the regional adjustment could increase overall program costs since shared savings payments would be impacted.

CMS also reviewed feedback on expanding the definition of the ACO regional service area to use a larger geographic area to determine regional FFS expenditures. In general, CMS expressed less concern regarding patient selection but would need additional time to consider a proposed framework for defining the alternative geographic area. This may be revisited in future rulemaking.

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 will 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. CMS believes this will 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 between BY3 and the performance year. However, the adjustment is subject to a cap of positive 3% for the agreement period. The cap is applied separately for each of the four enrollment types (ESRD, disabled, dual-eligible, and aged non-dual-eligible). 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 (i.e. ESRD, disabled and dual-eligible).

CMS evaluated three options to modify the cap: 1. account for changes in demographic risk scores before applying the 3% cap on positive adjustments resulting from changes in prospective HCC risk scores and apply in aggregate across the four enrollment types; 2. apply the 3% cap across all four enrollment types without first accounting for changes in demographic risk scores; and 3. allow the cap on the risk score growth to increase by a percentage of the difference between the 3% cap and risk score growth in the region (the percentage applied would be one minus the regional market share).

CMS decided to finalize the first option and will account for changes in demographic risk scores before applying the 3% cap on positive adjustments resulting from changes in prospective HCC risk scores. The cap will apply in aggregate across the four enrollment types.

Low-revenue ACOs. CMS finalized a policy to provide more flexibility in how certain ACOs can qualify for shared savings. The changes will 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 will 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, will 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 will 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 expressed 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 finalizes its proposal to allow ACOs that do not meet the minimum quality performance standard to 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 will be calculated on a sliding scale tied to the ACO's quality performance score. For ACOs in shared savings tracks, CMS will 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 will 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.

In the final rule, CMS also clarifies that the sliding scale approach will be applicable to all ACOs regardless of how they report their quality data. Through CY 2024, this includes ACOs that report quality data via the CMS Web Interface.

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 finalizes its proposal to extend the incentive to report the APP eCQMs/MIPS CQMs through the CY 2024 performance period. ACOs that opt to report the eCQMs/MIPS CQMs in the APP measure set will meet the minimum quality performance standard if they achieve both:

- A score of at least the 10th percentile on at least one of the four APP outcome measures; and
- A score at or above the 40th percentile on least one of the other five APP measures.

CMS's policies for applying its MSSP quality performance standard are detailed in the table below.

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 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.	To encourage APP measure reporting, if ACO reports all three 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 expressed 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 stated its belief 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 suggests 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 finalizes its proposal to adopt a "health equity adjustment" beginning with the CY 2023 performance period that it believes will better support those ACOs caring for large proportions of underserved patients while incentivizing high quality care for all populations that ACOs serve. CMS will 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 will be used to determine whether ACOs meet the MSSP quality performance standard. However, the health equity bonus points will be available to only those ACOs that successfully report the eCQMs/MIPS CQMs in the APP measure set.

The equity adjustment will be the product of two factors – a "measure performance scaler" and "an underserved multiplier." The measure performance scaler is unchanged

from the proposed rule, and will assign ACOs points on each APP measure based on whether they score in the top, middle or bottom third of performance on the measure. However, CMS adopts a modification to the underserved multiplier by including assigned beneficiaries that receive the Medicare Part D Low Income Subsidy (LIS). CMS indicates that because eligibility criteria for the LIS are the same nationally, the inclusion of the LIS proportion makes it a more nationally standardized measure of low income than dual eligibility. As a result, the underserved multiplier will be the higher of the ACO's Area Deprivation Index (ADI) score, its proportion of beneficiaries who are dually eligible for Medicare and Medicaid, or its proportion receiving the Part D LIS.

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

Step 1: Calculate the ACO's measure performance scaler. CMS will determine each ACO's performance on each APP measure in the MSSP. Then, for each measure, ACOs will be placed into one of three "performance groups" representing the top, middle and bottom third of performance on the measure. ACOs will 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 will sum the value assigned to each measure to determine the measure performance scaler, and the maximum value of the scaler will be 24. The table below drawn from the final 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 highest of three 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

- The proportion of the ACO's performance year assigned beneficiary population that are dually eligible for Medicare and Medicaid
- The proportion of the ACO's performance year assigned beneficiary population that receive the Medicare part D LIS

CMS will 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 will use each assigned beneficiary's most recent mailing address to determine their census block and thereby determine their ADI percentile rank. CMS also will 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 U.S. 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 U.S. dollars) Median gross rent (in U.S. dollars) Median monthly mortgage (in U.S. 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	Proportion of assigned beneficiaries that receive LIS	Underserved Multiplier (higher of A, B or C)
ACO 1	0.4	0.6	0.3	0.6
ACO 2	0.1	0.2	0.1	0.2
ACO 3	0.3	0.3	0.2	0.3
ACO 4	0.1	0.1	0.1	0.1
ACO 5	0.8	0.6	0.7	0.8
ACO 6	0.2	0.1	0.2	0.2

Step 3: Calculate the ACO's health equity adjustment bonus points. This calculation will 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	0.1	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

CHANGES TO THE QUALITY PAYMENT PROGRAM

The rule adopts 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 a second option for those participating in 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 updates its policies for MIPS Value Pathways (MVPs). CMS also finalizes 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 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%
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 an eventual 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 finalizes the adoption of five new MVPs that will be available beginning with the CY 2023 performance period: cancer care, kidney health, episodic neurological conditions, neurodegenerative conditions and promoting wellness. CMS also adopts updates to the seven MVPs that it adopted in last year's PFS final rule. Appendix 3 of the final rule includes the details of the measures included in each MVP. CMS also finalizes modifications to its processes for establishing and scoring MVP "subgroups" within larger physician practices, described in subsequent sections of this advisory.

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 adopts a process to obtain feedback on candidate MVPs in advance of formal rulemaking. Draft versions of MVP may be posted to the QPP website for 30 days, and CMS will 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 will, 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 finalizes its proposal to use Medicare part B claims as the data source for specialty type determination, rather than the Medicare Provider Enrollment, Chain and Ownership System (PECOS). As a result, a single specialty group will be defined as a group consisting of one specialty type using Medicare part B claim. A multispecialty group will be a group consisting of two or more specialty types, also determined by Medicare part B claims.

MVP Subgroup Registration. In prior rulemaking, CMS created the processes for establishing and registering subgroups for MVP participation. These processes remain largely unchanged, but CMS adopts two modifications. First, CMS will require subgroups to provide a description of the composition of the subgroup at the time of registration. CMS will allow registrants to write their own narratives, or select from a list of available descriptions. Second, CMS 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 adopts changes to how it will calculate performance for subgroups on measures that are calculated using administrative claims. In general, CMS will assign to 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 expands its definition of high priority measures to include health equity-related measures. Consistent with change, CMS also finalizes a new health-related social needs screening measure that will be available beginning with the CY 2023 reporting period. The measure is similar to the one CMS adopted for the hospital inpatient quality reporting program earlier this year. 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 finalizes its proposal 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 will raise the data completeness threshold to 75%. CMS believes this approach will ensure the MIPS program uses complete, accurate data.

CMS notes that this data completeness threshold does not apply to CMS Web Interface measures because they have a different set of data completeness requirements. Starting with the CY 2023 performance period, the web interface is only available to MSSP ACOs.

CAHPS for MIPS Case Mix Adjustment. The CAHPS for MIPS measure includes adjustment for patient characteristics that 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 finalizes its proposal 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 does not adopt any new measures for the MIPS cost category, and finalizes minimal changes to the category's requirements. However, to conform to statutory requirements, CMS will establish a cost improvement score of up to one 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 adopts 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 finalizes several changes to the Promoting Interoperability performance category. These changes mirror many of the same changes that CMS adopted for the hospital Promoting Interoperability program in the FY 2023 Inpatient PPS final rule.

Query of Prescription Drug Monitoring Program Measure. CMS will require the reporting of the Electronic Prescribing objective's Prescription Drug Monitoring Program (PDMP) measure. The measure will continue to have 10 points associated with its reporting but will no longer be considered bonus points. The measure requires a "yes/no" response. In addition, CMS will expand the measure to include Schedule II, III and IV drugs, instead of just Schedule II drugs. CMS believes this expansion will facilitate more informed prescribing practices and improve patient outcomes.

Of note, CMS will 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 will 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 will 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 change, MIPS eligible clinicians will 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 Enabling Exchange Under TEFCA measure.

Levels of Active Engagement for Measures in Public Health and Clinical Data Exchange Objective. CMS will 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 will also require the reporting of the level of active

engagement for the measures under the objective beginning with the CY 2023 EHR reporting period.

Finally, MIPS eligible clinicians will be permitted to spend only one performance period at the Pre-production and Validation level of active engagement per measure. They will be required to progress to the Validated Data Production level in the next performance period for which they report a particular measure.

Scoring Methodology. CMS adopts several changes to points for each meaningful use objective. CMS will 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 will increase the number of points associated with the Public Health and Clinical Data Exchange objective from 10 to 25 points. CMS will 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.

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 measures: • Syndromic Surveillance Reporting • Public Health Registry Reporting • Clinical Data Registry Reporting	5 points (bonus)	5 points (bonus)

CMS also will 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 will not continue the reweighting policy for nurse practitioners, physician assistants, clinical nurse specialists and certified registered nurse anesthetists.

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 will 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.

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 will 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.

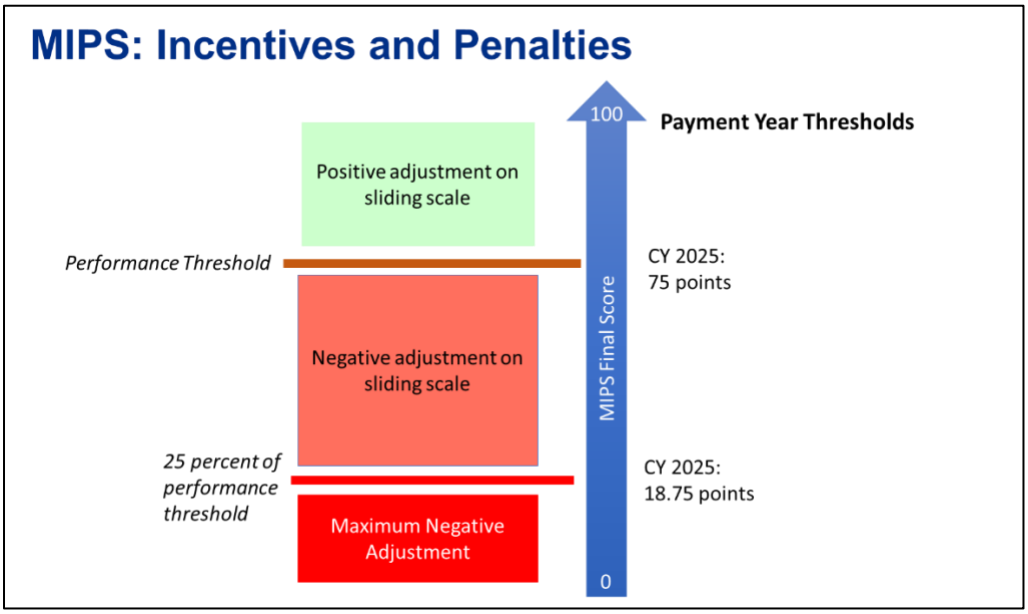
As outlined in Figure 1, CMS is required by law to identify two final score thresholds to translate MIPS final scores into a payment adjustment:

- **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 2025 MIPS payment adjustments, the performance period is CY 2023.

  For the CY 2023 performance/CY 2025 payment years, CMS will 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 will 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 will 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 will instead apply the 50-clinician limit at the APM entity level. CMS will identify clinicians by using the TIN/NPIs on the APM Entity's participation list.