CY 2022 Medicare Physician Fee Schedule and Quality Payment Program Proposed Rule

On July 13, 2021 CMS released the CY 2022 Medicare Physician Fee Schedule (MPFS) proposed rule. CMS notes that the MPFS is one of several proposed rules that reflect a broader Administration-wide strategy to create a health care system that results in improved accessibility, quality, affordability, empowerment, and innovation. Comments are due September 13, 2021. For additional information please see CMS's CY 2022 MPFS Fact Sheet. Details on key provisions of the proposed rule are provided below.

Table of Contents

A. Telehealth and Other Services Involving Communications Technology (section II.D.)

Proposed Changes

- **Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis**

Proposing to retain all services added to the Medicare telehealth services list on a Category 3 basis until end of CY 2023.

- **Implementation of Provisions of the Consolidated Appropriations Act, 2021 (CAA)**

Implementing the changes made in the CAA to open mental telehealth services up by removing geographic restrictions and allowing the patient's home as a permissible originating site. To implement this CMS is proposing, as a condition of payment for mental health telehealth services, the billing physician or practitioner must have furnished an in-person, non-telehealth service to the beneficiary within 6-month period before the date of the telehealth services.

CMS is also proposing to require that an in-person, non-telehealth service must be furnished for the diagnosis, evaluation, or treatment of mental health disorders by the same practitioner, other than for treatment of a diagnosed SUD or co-occurring mental health disorder, and that the distinction between the telehealth and non-telehealth services must be documented in the patient's medical record.

Proposing that there would need to be an in-person visit within 6 months of any telehealth service furnished for the diagnosis, evaluation, or treatment of mental health disorders, and the in-person visit would need to

be documented in the patient's medical record. Payment would not be made for these telehealth services unless the required in -person service was furnished within 6 months of the telehealth service.

Proposing to amend the regulations to conform with the statutory change to include rural emergency hospitals as telehealth originating sites beginning in CY 2023. In accordance with the Act added by section 125(c) of the CAA, CMS proposes to revise their regulations to add a rural emergency hospital, as a permissible originating site for telehealth services furnished on or after Jan 1, 2023.

- **Payment for Medicare Telehealth Services Furnished Using Audio-Only Communication Technology**

CMS is also proposing to revise the regulatory definition of "interactive telecommunications system" to permit use of audio only communication technology for mental health services under certain conditions when provided to beneficiaries located in their home. Specifically, CMS is proposing to amend their regulation at § 410.78(a)(3) to define interactive telecommunications system to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to establish patients when the originating site is the patient's home. CMS is further proposing to adopt a similar ongoing requirement that an in-person item or service must be furnished within 6 months of such a mental health telehealth services.

CMs is also proposing to limit payment for audio-only services to services furnished by physicians or practitioners who have the capacity to furnish two-way, audio/video telehealth services but are providing the mental health services via audio-only communication technology in an instance where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology.

CMS is proposing to develop a service-level modifier that would identify mental health telehealth services furnished to beneficiaries in their home using audio-only communications technology.

- **Permanent adopting coding and payment for HCPCS code G2252**

In the CY 2021 PFS final rule, CMS established HCPCS code G2252 (brief communication technology-based by a physician or other QHCP who can report e/m services, provided to an established patient) on an interim basis. CMS is proposing to make this a permanent code.

Background/Rationale

- **Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis**

In FY 2021 CMS created a third category of telehealth services, Category 3, for those services CMS believed there is a likely clinical benefit when furnished via telehealth, but for which there was not enough clinical data to make it a permanent addition under Category 1 or 2. CMS added 135 services to Medicare telehealth list on an interim basis through the IFR and a subregulatory process. They have since added additional services on a temporary basis.

By extending the Category 3 status of certain telehealth services, it will allow CMS time to collect more information regarding utilization of these services during the pandemic and provide stakeholders the opportunity to continue to develop support for the permanent addition of appropriate services to the

telehealth list through CMS' regular consideration process, which includes notice-and-comment rulemaking. By keeping these services on the Medicare telehealth list through CY 2023, CMS will facilitate the submission of requests to add services permanently to the Medicare telehealth service list for consideration in the CY 2023 PFS rulemaking process and for consideration in the CY 2024 PFS rule.

The table below represents services that were added to the Medicare Telehealth services list on an interim basis to respond to the PHE, but were not extended on a temporary Category 3 basis:

	Service Type	**Codes**
Category 2	Domiciliary or rest home visits	99324-99328
	Home visits	99341-99345
	Office/outpatient services	99441-99442
	Neurological & Psychological Testing	96130-96133

- **Implementation of Provisions of the Consolidated Appropriations Act, 2021 (CAA)**

CMS chose this 6-month timeline because they are concerned that less than 6 months may impose potentially burdensome travel requirements on the beneficiary, but that an interval greater than 6 months could result in the beneficiary not receiving clinically necessary in-person/observation. The proposed 6-month interval also matches the specified statutory interval for the initial telehealth service. CMS believes that a 6-month interval strikes an appropriate balance between these compete considerations.

- **Payment for Medicare Telehealth Services Furnished Using Audio-Only Communication Technology**

Historically, CMS has not proposed any permanent modifications to the definition of interactive telecommunications system to allow for use of audio-only communications technology due to our interpretation of the statutory requirements, as well as concerns over program integrity and quality of care. CMS was concerned that the use of audio-only communications technology for Medicare telehealth services could lead to inappropriate overutilization and believed that video visualization of the patient generally was necessary to fulfill the scope of the service elements of the codes included on the Medicare Telehealth list. However, CMS has noticed that many populations, including vulnerable and rural populations have come to rely on the use of audio-only mental health visits which is why they are now proposing to expand the definition of interactive telecommunications system to include audio-only.

CMS believes limiting use of the audio only to this specific group of practitioners will ensure that mental health services furnished via telehealth are only conducted using audio-only communication technology in instances where the use of audio-only technology is facilitating access to care that would be unlikely to occur otherwise, given the patient's technological limitations or preferences.

- **Permanent adopting coding and payment for HCPCS code G2252**

CMS agreed with commentators that stated the code accommodates beneficiaries and practitioners who may be reluctant to return to primarily in-person services post-PHE.

Comments:

- **Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis**

CMS is seeking comment on any of the CPT they rejected from receiving Category 1 or 2 status, as well as the codes that will not have Category 3 status post PHE.

- **Implementation of Provisions of the Consolidated Appropriations Act, 2021 (CAA)**

Seeking comment on whether CMS should adopt a claims-based mechanism to distinguish between the mental health telehealth services that are within the scope of the CAA amendments and those that are not, and if so, what that mechanism should be in. CMS is also seeking comment on whether the required in-person, non-telehealth service could also be furnished by another physician or practitioner of the same specialty and same subspecialty within the same group as the physician or practitioner who furnishes the telehealth service. CMS is also interested in receiving comments regarding the extent to which a patient routinely receiving mental health services from one practitioner in a group might have occasion to see a different practitioner of the same specialty in that group for treatment of the same condition. Also seeking comment on whether the 6-month interval is good or if they should consider another interval that is either shorter or longer. Seeking comment on whether it would be appropriate to establish a different interval for telehealth services administered via audio only mechanisms vs. two-way audio/video.

- **Payment for Medicare Telehealth Services Furnished Using Audio-Only Communication Technology**

CMS is seeking comment on these proposals, as well as what, if any, additional documentation should be required in the patient's medical record to support he clinical appropriateness of providing audio-only telehealth services for mental health in the even of an audit or claims denial. CMS is also seeking comment on whether for the purposes of audio-only mental health telehealth services exception, CMS should exclude certain higher-level services, such as level 4 or 5 E/M codes, when furnished alongside add-on codes for psychotherapy, or codes that describe psychotherapy with crisis. Finally, CMS is seeking comment on whether the full scope of service elements for these codes could be performed via audio-only communication technology.

- **Permanent adopting coding and payment for HCPCS code G2252**

As part of the broader COVID-19 flexibilities, on March 31st CMS changed the definition of "direct supervision" during the PHE for COVID-19 as it pertains to supervision of diagnostic tests, physicians' services, and some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using real-time audio/video technology, instead of in-person. This was extended in the 2021 PFS rule through December 31, 2021. CMS continues to seek information and feedback on whether this flexibility should be continued beyond the later of the of the end of the PHE or CY 2021, perhaps even permanent. Specifically, the extent to which the flexibility to meet the immediate

availability requirement for direct supervision using real-time, audio/video technology is being used during the PHE, and whether providers anticipate relying on this flexibility post PHE.

B. Valuation of Specific Codes

Proposed Changes

- **Remote Therapeutic Monitoring (CPT codes 989X1, 989X2, 989X3, 989X4, and 989X5)**

In this section, CMS proposes updated RUC-recommended work RVU values for CPT codes related to remote therapeutic monitoring. Specifically, they propose CPT code 989X4 (Remote therapeutic monitoring treatment management services, physician/ other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes) has an RVU of 0.62.

They propose to assign the add on CPT code 989X5 (Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)) an RVU of 0.61. They are also proposing the RUC-recommended direct PE inputs for the two treatment management codes, CPT codes 989X4 and 989X5, without refinement.

CMS proposes to refine the direct PE inputs for the three PE-only codes:

- CPT code 989X1 (Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment),
- CPT code 989X2 (Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days), and
- CPT code 989X3 (Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days).

CMS also proposes to value the PE for CPT code 989X1 by crosswalking to the PE RVU for RPM code 99453 upon which the new RTM code was based. CMS is also proposing to value the PE for CPT codes 989X2 and 989X3 by crosswalking to the PE RVU for comparable RPM code 99454, a code that includes payment for the medical device used to collect and transmit data.

- **Chronic Care Management (CCM) and Principal Care Management (PCM) (CPT codes 99490, 99439, 99491, 99X21, 99487, 99489, 99X22, 99X23, 99X24, and 99X25)**

For CY 2022, the RUC resurveyed the CCM code family, including Complex Chronic Care Management (CCCM) and Principal Care Management (PCM), and added five new CPT codes:

- 99X21 (CCM services each additional 30 minutes by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)). RUC recommended work RVU: 1.00
- 99X22 (PCM services for a single high-risk disease first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month). RUC recommended work RVU: 1.45
- 99X23 (PCM services for a single high-risk disease each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). RUC recommended work RVU: 1.00
- 99X24 (PCM services, for a single high-risk disease first 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month). RUC recommended work RVU: 1.00
- 99X25 (PCM services, for a single high-risk disease each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)). RUC recommended work RVU: .71

The CCM/CCCM/PCM code family now includes five sets of codes, each set with a base code and an add-on code. The sets vary by the degree of complexity of care, who furnishes the care, and the time allocated for the services. In this section CMS proposes to accept the RUC-recommended values for the 10 codes in the chronic care management family and are proposing to accept the recommended work values for the codes.

CMS is also proposing to adopt CPT codes 99X22 and 99X24 to replace HCPCS codes G2064 and G2065 in the calculation of the rate for HCPCS code G0511 for General Care Management services billed by RHCs and FQHCs. The payment rate for HCPCS code G0511 is calculated based on the average of the national non-facility PFS payment rate for care management and general behavioral health integration codes (CPT codes 99484, 99487, 99490, and 99491) as well as HCPCS codes G2064 and G2065 which describe PCM services billed under the PFS. The payment rate for HCPCS code G0511 is updated annually based on the PFS amounts for these codes.

Background/Rationale

- **Remote Therapeutic Monitoring**

CMS proposed these updated RUC-recommended work RVU values as a means of maintaining parity with the two RPM treatment management codes (CPT codes 99457 and 99458) upon which the two RTM codes are based.

- **Chronic Care Management and Principal Care Management**

CMS is adopting the RUC-recommended values for work RVUs and direct PE inputs for CY 2022, which derive from the recent RUC specialty society survey. They believe proposing to accept these updated values is consistent with their goals of ensuring continued and consistent access to these crucial care management services and acknowledges their longstanding concern about undervaluation of care management under the PFS.

Comments:

In this section, CMS requests comment on the following:

- The treatment management RTM codes (CPT codes 989X4 and 989X5) because they are not E/M codes, cannot be designated as care management services. As a result, CMS is seeking comment on how they might remedy the issues related to the RTM code construction in order to permit practitioners who are not physicians or NPPs to bill the RTM codes.
- The typical type of device(s) and associated costs of the device(s) that might be used to collect the various kinds of data included in the code descriptors (for example, respiratory system status, musculoskeletal status, medication adherence, pain) for the RTM services.
- Whether keeping professional PCM and CCM at the same value creates an incentive to bill CCM instead of billing PCM when appropriate.
- Changes in the work time for HCPCS code G0500, in the interest of gaining additional information about the typical use of this procedure.
- How billing practitioners furnishing CCM at different service sites (for example, physician office settings, RHCs, FQHCs) have been obtaining beneficiary consent over the past year and what levels of supervision are necessary to obtain beneficiary consent when furnishing CCM services.

C. Evaluation and Management Visits (section II.F.)

Proposed Changes

- **Split (or Shared) Visits**

In this section, CMS proposes to define a **"split (or shared) visit"** as an E/M visit in the facility setting that is performed in part by both a physician and an NPP who are in the same group, in accordance with applicable laws and regulations. They also propose to add this definition to a new section of regulations at § 415.140.

Additionally, CMS proposes to define split (or shared) visits as those that:

- Are furnished in a facility setting by a physician and an NPP in the same group, where the facility setting is defined as an institutional setting in which payment for services and supplies furnished incident to a physician or practitioner's professional services is prohibited under our regulation at § 410.26(b)(1).
- Are furnished in accordance with applicable law and regulations, including conditions of coverage and payment, such that the E/M visit could be billed by either the physician or the NPP if it were furnished independently by only one of them in the facility setting (rather than as a split (or shared) visit).

CMS proposes to revise § 415.140 to codify this definition.

CMS is also proposing to modify the policy to allow physicians and NPPs to bill for split (or shared) visits for both new and established patients, and for critical care and certain Skilled Nursing Facility /Nursing Facility (SNF/NF) E/M visits.

Background/Rationale

- **Split (or Shared) Visits**

CMS is updating the definition of split (or shared) visits because they believe that limiting the definition to include only E/M visits in institutional settings, for which "incident to" payment is not available, will clarify the policies applicable to split (or shared) visits, from the policies applicable to services furnished incident to the professional services of a physician. CMS does not see a need for split (or shared) visit billing in the office setting, because the "incident to" regulations govern situations where an NPP works with a physician who bills for the visit, rather than billing under the NPP's own provider number.

CMS is also proposing to modify the policy to allow physicians and NPPs to bill for split (or shared) visits for both new and established patients, and for critical care and certain Skilled Nursing Facility /Nursing Facility (SNF/NF) E/M visits. They are proposing these modifications to the current policy and conditions of payment for split (or shared) visits, to account for changes that have occurred in medical practice patterns, including the evolving role of NPPs as part of the medical team.

D. Billing for Physician Assistant Services (section II.G.)

Proposed Changes

- **Physician Assistant Billing and Payment Rights**

Section 403 of the Consolidated Appropriations Act, 2021 (CAA) amends section 1842(b)(6)(C)(i) of the Act to remove the requirement to make payment for Physician Assistant (PA) services only to the employer of a PA effective January 1, 2022. With the removal of this requirement, PAs will be authorized to bill the Medicare program and be paid directly for their services in the same way that Nurse Practitioners (NPs) and Certified Nurse Specialists (CNSs) do. Effective with this amendment, PAs also may reassign their rights to payment for their services and may choose to incorporate as a group comprised solely of practitioners in their specialty and bill the Medicare program, in the same way that NPs and CNSs may do.

Additionally, a new paragraph is proposed to be added to § 410.150(b)(15)(ii), which stipulates that payment will be made to a PA for professional services furnished by a PA in all settings in both rural and non-rural areas; and that payment is made only if there are no facility or other provider charges or is paid any amount for services furnished by a PA.

Background/Rationale

- **Physician Assistant Billing and Payment Rights**

With the proposed changes to PA billing and payment rights, CMS intends to broaden the scope of provider types that can bill services to the Medicaid program. This action is likely an attempt to address the coming primary care physician shortage and improve access to care for vulnerable and underserved populations.

E. Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests (section II.I.)

Proposed Changes

- **Reducing Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests by 2030**

Section 122 of the Consolidated Appropriations Act (CAA) of 2021, *Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests*, amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies.

The proposed rule implements this section, which phases out coinsurance by 2030 for colorectal screenings, regardless of whether other services like tissue removal occur in the same clinical encounter as the colorectal cancer screening test. Currently, colorectal screenings as a preventive service are furnished pre-deductible and with zero coinsurance. However, the addition of any procedure beyond a planned colorectal cancer screening test results in the beneficiary having to pay coinsurance.

The reduced coinsurance will be phased-in beginning January 1, 2023 and apply pre-deductible. Ultimately, the coinsurance will be zero for services furnished after January 1, 2030.

Specifically, CMS proposed to amend § 410.152(l)(5) to provide that Medicare payment in a specified year is equal to a specified percent of the lesser of the actual charge for the service or the amount determined under the fee schedule that applies to the test.

The phased in Medicare payment percentages for colorectal cancer screening services described in the proposed regulation at § 410.37(j) (and the corresponding reduction in coinsurance) are as follows:

- **80 percent payment for services furnished during CY 2022** (with coinsurance equal to 20 percent);
- 85 percent payment for services furnished during CY 2023 through CY 2026 (with coinsurance equal to 15 percent);
- 90 percent payment for services furnished during CY 2027 through CY 2029 (with coinsurance equal to 10 percent); and
- 100 percent payment for services furnished from CY 2030 onward (with coinsurance equal to zero percent).

Note that the 20 percent coinsurance under these circumstances will apply in CY 2022, reduced to 15 percent starting January 2023 (see bullets below). CMS notes that only flexible screening sigmoidoscopies and screening colonoscopies are recognized currently as colorectal cancer screening tests that might involve removal of tissue or other matter, for purposes of preventive services applicable to this rule.

Background/Rationale

- **Reducing Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests by 2030**

Previous comments have indicated concern that a coinsurance percentage applies (20 or 25 percent depending upon the setting) under circumstances where patients expected to receive only a colorectal screening test to which coinsurance does not apply under current law and regulations.

F. Vaccine Administration Services (section II.J.)

Proposed Changes

- **Increased Payment Rates to Administer COVID-19 Vaccine**

Medicare Part B covers both the vaccine and administration for the following vaccines: influenza, pneumococcal, HBV and COVID-19 vaccines. There is no applicable beneficiary coinsurance, and the annual Part B deductible does not apply for these vaccinations or services to administer them. Payments for COVID-19 vaccines and vaccine administration would be made in same manner as payments for influenza and pneumococcal vaccines. A payment rate has been assigned to administer preventive vaccines under the Outpatient Prospective Payment System (OPPS) and these rates are for hospitals and home health agencies for preventive vaccine administration. These rates have been geographically adjusted based on provider's wage index.

- **Payment for COVID-19 Vaccine Administration in the Home**

During the PHE a new add-on payment with national rate of $35.50 was established for when the vaccine is administered in the home of the beneficiary. Under this policy, providers and suppliers can bill Medicare using one of the existing COVID-19 vaccine administration CPT codes. Medicare will make this payment when either of these situations occur:

- patient has difficulty leaving home to get vaccine:
    - They have a condition, due to an illness or injury, that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver
    - they have a condition that makes them more susceptible to contracting a pandemic disease like COVID-19
    - They are generally unable to leave the home, and if they do leave home, it requires a considerable and taxing effort
- patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID-19 vaccine in settings other than their home

Background/Rationale

- **Medicare Part B Payment for Vaccines**

Medicare does not pay providers and suppliers for the vaccine product when the federal government purchases it and gives it to the provider or suppliers for free, as has been the case for all COVID-19 vaccines as of the publication of this proposed rule. It is noted that vaccine administration services are not technically valued or paid under the PFS because they are not included within the statutory definition of physicians' services. But historically based payment rates for the administration of these preventive vaccines by suppliers are being used to establish payment rates for the PFS.

- **Payment for COVID-19 Vaccine Administration in the Home**

For purposes of this add-on payment for in-home COVID-19 vaccine administration, a home is announced as a private residence temporary lodging (for example, a hotel or motel, campground, hostel, or homeless

shelter), an apartment in an apartment complex or a unit in an assisted living facility or group home, or a patient's home that is made provider-based to a hospital during the PHE for COVID-19.

The following locations are not to be considered as a patient's home: communal spaces of a multi-unit living arrangement; hospitals; Medicare SNFs, and Medicaid NFs, assisted living facilities, hospitals and skilled nursing facilities.

Comments:

CMS is requesting feedback from stakeholders that would support the development of an accurate and stable payment rate for administration of the preventive vaccines described in section 1861(s)(10) of the Act for physicians, NPPs, mass immunizers and certain other providers and suppliers. These specific questions can be found on page 303-305.

G. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (sections III.A., III.B., and III.C.)

Proposed Changes

- **RHC Payment Limit Per-Visit**

Under Section 130 of the CAA, the payment limits for RHCs were restructured starting on April 1, 2021. RHCs will begin to receive an increase in their payment limit per visit over an 8-year period, with a prescribed amount for each year from 2021 through 2028. Subsequent years will be increased by the percentage increase in the MEI applicable to primary care services furnished as of the first of such year.

For provider-based RHCs that had a per visit payment amount (or AIR) established for services furnished in 2020, the payment limit per visit shall be set at an amount equal to the greater of: (1) the per visit payment amount applicable to such RHC for services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021; or (2) the national statutory payment limit for RHCs per visit. In a subsequent year (that is, after 2021), the provider based RHC's payment limit per visit shall be set at an amount equal to the greater of: (1) the payment limit per visit established for the previous year, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of such subsequent year; or (2) the national statutory payment limit for RHCs.

For provider-based RHCs that meet certain requirements but did not have a per visit payment amount (or AIR) established for services furnished in 2020, the payment limit per visit shall be at an amount equal to the greater of: (1) the per visit payment amount applicable to the provider-based RHC for services furnished in 2021; or (2) the national statutory payment limit for RHCs. In a subsequent year (that is, after 2022), the provider based RHCs payment limit per visit will be the greater of: (1) the payment limit per visit established for the previous year, increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such subsequent year; or (2) the national statutory payment limit for RHCs. Beginning April 1, 2021, in accordance with section 130 of the CAA 2021, all RHCs are now subject to a payment limit.

- **Payment for Attending Physician Services Furnished by RHCs or FQHCs to Hospice Patients**

Implementing Section 132 of the CAA, which provided the authority for both FQHCs and RHCs to receive payment for hospice attending physician services, CMS is proposing to allow a physician, NP, or PA who is employed by or working under contract with an RHC or FQHC to provide hospice attending physician services during a time when they are working for that entity.

- **Concurrent Billing for Chronic Care Management Services (CCM) and Transitional Care Management (TCM) Services for RHCs and FQHCs**

CMS is proposing to allow RHCs and FQHCs to bill for TCM and other care management services furnished for the same beneficiary during the same service period, provided all requirements for bill are met.

- **Telecommunications Technology**

CMS proposes modifying the current regulatory definition of a mental health visit to provide for remote telehealth access to RHC and FQHC services in a manner similar to mental health services under the broader Physician Fee Schedule changes. Specifically, CMS is proposing to revise the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (in person) encounter and instead allow the service to be furnished through interactive, real-time telecommunications technology. This flexibility will only apply for purposes of diagnosis, evaluation, or treatment of a mental health disorder.

CMS is also proposing to allow RHCs and FQHCs to furnish mental health visits using audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction.

RHCs and FQHCs would not be permitted to report visits furnished using asynchronous communications like email exchanges. RHCs and FQHCs would also generally not be permitted to report Medicare telehealth services under section 1834(m) of the Act or be paid under the PFS since RHCs and FQHCs are not authorized to serve as distant site practitioners for Medicare telehealth services once the PHE for the COVID-19 pandemic has terminated.

Background/Rationale

- **RHC Payment Limit Per-Visit**

CMS is implementing regulations required by Section 130 of the CCA of 2021.

- **Payment for Attending Physician Services Furnished by RHCs or FQHCs to Hospice Patients**

Implementing Section 132 of the CAA.

- **Concurrent Billing for Chronic Care Management Services (CCM) and Transitional Care Management (TCM) Services for RHCs and FQHCs**

Currently, RHCs and FQHCs may not bill for TCM services for a beneficiary if another practitioner or facility has already billed for CCM services for the same beneficiary during the same time-period. CMS is proposing changes to this policy in order to align with broader shifts in CCM and TCM billing policy across settings.

- **Telecommunications Technology**

CMS wants to ensure that there is parity in the delivery of telehealth services between services provided in RHCs and FQHCs and those provided in other contexts governed by the PFS. Thus, CMS is proposing changes to RHC and FQHC telehealth flexibilities aligned with changes in other contexts.

Comments:

- **Telecommunications Technology**

Section 123 of the CAA required that there be an in-person service within 6 months prior to the furnishing of the telehealth service and at intervals thereafter as specified by the secretary for mental health services furnished via Medicare telehealth. CMS seeks comment on whether it should consider a similar requirement for mental health services furnished by RHCs and FQHCs or if such a requirement would be especially burdensome for beneficiaries receiving treatment at these facilities (e.g. in rural areas).

- **Paying all HIS and Tribally-Operated Outpatient Clinics the AIR**

The Tribal Technical Advisory Group (TTAG) has requested that CMS amend its Medicare regulations to make all IHS and tribally operated outpatient facilities eligible for payment at the IHS Medicare outpatient per visit rate / AIR. The TTAG explained that outpatient clinics, which are otherwise similar to grandfathered tribal FQHCs, are paid at different rates depending upon whether they meet the requirements as a "provider-based facility," a "grandfathered tribal FQHC," a non-grandfathered tribal FQHC, or none of the above. Instead, they would prefer that rates vary based on actual cost of the facility.

CMS is soliciting comment on the TTAG's request for CMS to amend its Medicare regulations to make all HIS and tribally operated outpatient facilities/clinics eligible for payment at the Medicare outpatient per visit rate/AIR, regardless of whether they were owned, operated, or leased by IHS. CMS seeks information on the kinds of and number of facilities or clinics that could potentially enroll in Medicare as an FQHC, or are already an FQHC paid under the FQHC PPS, and if these clinics are freestanding or provider-based to expand on information provided by the IHS profile. CMS also seeks information regarding the relative operating costs of these facilities and feedback and/or evidence showing why payment set at the HIS AIR would be more appropriate than payment rate under the FQC PPS. CMS also seeks comment on how IHS AIR relates to the costs in such clinics and the kinds of services that the clinics furnish. Finally, CMS seeks comment on the concerns that the AI/AN community may have on issues regarding access or inequity where a payment differential exists.

H. Medicare Part B Drug Payment for Drugs Approved under Section 505(b)(2) of the Federal Food, Drug, & Cosmetic Act (section III.E.)

Proposed Changes

- **505(b)(2) Approved Drugs Payment Framework**

The first portion of the framework would compare certain qualities of the section 505(b)(2) drug product with drug products already assigned to an existing multiple source drug code. This includes comparison of the: (1) active ingredient(s); (2) dosage form (if part of the drug product name); (3) salt form; and (4) other

ingredients in the drug product formulation. The drug product assessment could result in a match or non-match designation. Section 505(b)(2) drug products receiving a match designation in the first portion of the framework would continue to a verification step. This step would compare the pharmacokinetic and clinical studies of the section 505(b)(2) drug product's FDA-approved labeling with those of the drug products already assigned to an existing multiple source code. Finally, a determination would be made as to whether the section 505(b)(2) drug product could be assigned to the existing multiple source code.

Background/Rationale

- **505(b)(2) Approved Drugs Payment Framework**

For a subset of drugs that are approved by the FDA under a New Drug Application approved through the 5050(b)(2) pathway the distinction between multiple source drugs and single source drugs are less straightforward than those drugs approved under 505(b)(1). Approximately 10-20 percent of the section 505(b)(2) drug products approved share substantial portions of the FDA-approved labeling with the approved drug product(s) upon which the section 505(b)(2) application relied. IN some cases, the section 505(b)(2) drug product even shares substantial portions of labeling with generic drug products that are payable under Part B as multiple source drugs. Medicare Part B data from 2020 indicate that spending for some of these section 505(b)(2) drug products (that is, those drug products that could be assigned to a multiple source drug code under the proposed framework described above, but are instead currently assigned to a single source drug code) is substantially greater than that for corresponding generic drug products assigned to a multiple source drug code.

Comments:

- CMS is seeking comment on:
    - The framework and how it aligns with the statutory definitions of single source and multiple source drugs in section 1847A(c)(6)(C) and (D) of the Act, respectively;
    - How the framework distinguishes situations in which a section 505(b)(2) drug product is not described by an existing multiple source drug code; and
    - The potential impacts of the framework on Medicare beneficiaries, the government, and other stakeholders.

I. Removal of Select National Coverage Determinations (section III.G.)

Proposed Changes

- **Enteral and Parenteral Nutritional Therapy (NCD Manual Citation: 180.2)**

CMS is proposing to remove NCD 180.2 Enteral and Parenteral Nutritional Therapy (July 11, 1984). CMS believes that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.

- **Positron Emission Tomography (PET) Scans (NCD Manual Citation: 220.6)**

CMS is proposed to remove NCD 220.6 Positron Emission Tomography (PET) Scans (September 3, 2013). CMS believes that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.

Background/Rationale

CMS periodically identifies and removes National Coverage Determinations (NCDs) that no longer contain clinically pertinent and current information, in other words those items and services that no longer reflect current medical practice, or that involve items or services that are used infrequently by beneficiaries. Eliminating an NCD that provides national coverage for items and services means that the item or service will no longer be automatically covered by Medicare (42 CFR 405.1060). Instead, the initial coverage determinations for those items and services will be made by local Medicare Administrative Contractors (MACs). In the CY 2021 PFS final rule, CMS did not establish an exclusive list of criteria for identifying and evaluating NCDs for removal. Instead, they added a new set of considerations to the six factors established in 2013 rulemaking. Those new considerations are:

- General age of an NCD,
- Changes in medical practice or standard of care,
- Pace of medical technology development since the last determination; and
- Availability and quality of clinical evidence and information to support removal of an NCD.

In addition to these new considerations, CMS would consider proposing the removal of an NCD if:

- They believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.
- The technology is generally acknowledged to be obsolete and is no longer marketed.
- In the case of a noncoverage NCD based on the experimental status of an item or service, the item or service in the NCD is no longer considered experimental.
- The NCD has been superseded by subsequent Medicare policy.
- The national policy does not meet the definition of an "NCD" as defined in sections 1862(l) or 1869(f) of the Act.
- The benefit category determination is no longer consistent with a category in the statute.

CMS received comments to the NCD Removal proposal in response to the CY 2021 PFS proposed rule suggesting another seven NCDs to consider removing. After reviewing those comments and considering other available evidence and information, CMS is proposing to remove one of those seven NCDs in this rulemaking cycle. CMS have opened a national coverage analysis (NCA) using the NCD process for one and believe the other five NCDs should be retained.

- **Enteral and Parenteral Nutritional Therapy (NCD Manual Citation: 180.2)**

External stakeholders suggested to CMS that portions of this NCD are outdated. CMS has determined that this NCD unnecessarily adds to patient and provider burden as it requires repeated reviews of medical necessity for those individuals who need enteral or parenteral nutrition services as a result of chronic diseases that affect the ability to eat or to digest/absorb nutrition. Local contractors have proposed LCDs that, if finalized, would provide parenteral and enteral nutrition coverage for certain Medicare beneficiaries.

- **Positron Emission Tomography (PET) Scans (NCD Manual Citation: 220.6)**

NCD 220.6 established broad national non-coverage for non-oncologic indications of PET and was established in 2000. In 2013, CMS reconsidered the NCD to allow coverage for diagnostic PET imaging

for oncologic uses not already determined by an NCD, to be made at the discretion of local MACs. Since the 2013 reconsideration, new non-oncologic PET agents have been approved by the FDA and multiple professional medical societies have published guidelines relevant to appropriate use of these agents. CMS believes that local contractor discretion provides an immediate avenue to potential coverage in appropriate candidates for non-oncologic indications. For clarity, CMS is not proposing to change any other subsections of 220.6. Thus, the NCDs listed at 220.6.1 through 220.6.20 would not be changed by this proposal.

Comments:

CMS is soliciting comments on the proposal to remove the two NCDs, as well as comments recommending other NCSs for CMS to consider for future removal. Public comments will help inform CMS's decision to take one of three actions on the three NCDs proposed for removal:

- Remove the NCD, as proposed, allowing for coverage to be determined by the MACs.
- Retain the current policy as an NCD.
- Reconsider the NCD by opening a National Coverage Analysis.

Comments suggesting that the NCD should be revised, rather than eliminated, should include new evidence that was not previously available at the time of the original NCD or at the time the NCD was last reconsidered, in order to support a change in national coverage.

J. Medicare Shared Savings Program (section III.J.)

Proposed Changes

- **Amend APM Performance Pathway Reporting Requirements**

CMS is proposing a longer transition for Accountable Care Organizations (ACOs) reporting electronic clinical quality measure/Merit-based Incentive Payment System clinical quality measure (eCQM/MIPS CQM) all-payer quality measures under the Alternative Payment Model (APM) Performance Pathway (APP), by extending the availability of the CMS Web Interface collection type for two years, through performance year (PY) 2023.

- **Freeze Quality Performance Standard for One Year**

CMS is proposing to freeze the quality performance standard for PY 2023, by providing an additional one-year before increasing the quality performance standard ACOs must meet to be eligible for shared savings, and additional revisions to the quality performance standard to encourage ACOs to report all-payer measures.

- **Revise Repayment Mechanism**

CMS is proposing to revise the methodology for calculating repayment mechanism amounts for risk based ACOs to reduce the percentage used in the existing amount by 50%. ACOs accepting performance-based risk must establish a repayment mechanism (i.e, escrow, line of credit, surety bond) to assure CMS that they can repay losses for which they may be liable upon reconciliation.

Additionally, CMS is proposing to modify the threshold for determining whether an ACO is required to increase its repayment mechanism amount during its agreement period. These proposals would result in

lower required initial repayment mechanism amounts, and less frequent repayment mechanism amount increases during an ACO's agreement period.

A onetime opportunity for certain ACOs that established a repayment mechanism to support their participation in a two-sided model beginning on July 1, 2019; January 1, 2020; or January 1, 2021; to elect to decrease the amount of their existing repayment mechanisms is also proposed.

- **Streamline Application Process**

CMS is proposing to reduce administrative burden and streamline the Shared Savings Program application process by modifying the prior participation disclosure requirement, so that the disclosure is required only at the request of CMS during the application process.

- **Reduce Frequency of Submission of Sample Participant Agreements**

CMS is also proposing to reduce the frequency and circumstances under which ACOs submit sample ACO participant agreements and executed ACO participant agreements. Under this proposal:

  - § 425.204(b) would be modified so that the prior participation disclosure requirement is prescribed only at the request of CMS during the application process—rather than as a mandatory submission with the ACO's initial or renewal application.
  - Sample ACO participant agreements and the first and signature pages of each executed ACO participant agreement would need to be submitted during the application process only if requested by CMS, rather than as a mandatory submission with the ACO's initial or renewal application. The ACO must still certify that all its ACO participant agreements comply with the regulatory requirements of the Shared Savings Program.
  - § 425.116(c) would be modified to remove provisions requiring an ACO to submit an executed ACO participant agreement for each ACO participant at the time of its initial application or participation agreement renewal process. We would retain the requirement that an ACO must submit an executed ACO participant agreement for each ACO participant that it requests to add to its list of ACO participants.

- **Amend Beneficiary Notification**

CMS is proposing to amend the beneficiary notification requirement to set forth different notification obligations for ACOs depending on the assignment methodology selected by the ACO to help avoid unnecessary confusion for beneficiaries. Specifically, CMS is proposing:

  - to change § 425.312(a)(2)(ii) so that in the case of an ACO that has selected preliminary prospective assignment, the ACO or ACO participant must provide the standardized written beneficiary notice to each fee-for-service beneficiary prior to or at the first primary care visit of the performance year.
  - to add at § 425.312(a)(2)(iii) that, in the case of an ACO that has selected prospective assignment, the ACO or ACO participant must provide the standardized written notice to each prospectively assigned beneficiary prior to or at the first primary care visit of the performance year.

- **Revision to Definition of Primary Care Services**

CMS is proposing revisions to the definition of primary care services that are used for purposes of beneficiary assignment. The proposed changes would be applicable for determining beneficiary assignment beginning with PY 2022 and consist of:

- Chronic Care Management (CCM) CPT code 99X21, if finalized through the CY 2022 PFS rulemaking;
- Principal Care Management (PCM) CPT codes 99X22, 99X23, 99X24, and 99X25, if finalized through the CY 2022 PFS rulemaking;
- Prolonged office or other outpatient evaluation and management (E/M) service HCPCS code G2212; and
- Communication Technology-Based Service (CTBS) HCPCS code G2252 if payment for this code is made permanent through the CY 2022 PFS rulemaking.

Background/Rationale

- **Amend APM Performance Pathway Reporting Requirements**

This proposal aims to give ACOs more time to comply with the eCQM/MIPS CQM reporting requirements by two years. This allows more time to prepare for vendor selection, implementation, and testing of new systems used by ACOs.

- **Freeze Quality Performance Standard for One Year**

CMS is proposing to freeze quality performance standards at the 30th percentile to provide additional time for both ACOs and EHR vendors to put in place processes and systems, such that ACOs will be well positioned to report eCQM/MIPS CQMs by performance year 2024.

- **Revise Repayment Mechanism**

This set of proposals is intended to lower barriers to participation for ACOs' in two-sided models and increase available resources for investment in care coordination and quality improvement activities. CMS hopes these proposals improve participation in two-sided risk models by ACOs.

- **Streamline Application Process**

This proposal is aimed at reducing the administrative burden of applying to participate in the MSSP program, with the goal of improving participation in MSSP in response to reduction of participants over the last few years.

- **Reduce Frequency of Submission of Sample Participant Agreements**

CMS is attempting to removing the requirements to submit sample agreements to reduces administrative burden on both ACOs and CMS in the submission and reviewing of sample agreements.

- **Amend Beneficiary Notification**

This proposal is aimed at removing unnecessary communication with beneficiaries who could be confused by the notifications they are receiving from ACOs, CMS, health insurers, and providers.

- **Update Definition of Primary Care Services**

This proposal is seeking to align beneficiaries more accurately with the providers managing their care for an ACO. In particular it takes into account the expansion of telehealth services, allowing beneficiaries to be assigned to physicians they have seen through telehealth visits.

Comments:

- CMS is seeking comment on the proposed updates to reporting requirements under the APP for performance year 2022 and subsequent years.
- CMS is seeking comment on whether they should extend the CMS Web Interface collection type for more than the proposed two years.
- Comments are sought on addressing health disparities and promoting health equity through the all-payer eCQM/MIPS CQM.
- Comments are sought on the feasibility of TIN level reporting and sampling for eCQMs/MIPS CQMs.
- CMS is seeking comments on reporting options for specialist providers within an ACO.
- CMS is seeking comments on publicly displaying prior year performance scores that equate to the 30th and 40th percentile MIPS Quality performance category scores.
- Comments are sought on considerations related to the use of regional FFS expenditures in the Shared Savings Program's benchmarking methodology.

K. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan (section 2003 of the SUPPORT Act) (section III.Q.)

Proposed Changes

- **Posed Timeframe for EPCS Adoption**

This section proposes to revise 42 CFR § 422.160(a)(5) to change the EPCS compliance date from January 1, 2022 to January 1, 2023. They also propose to extend the compliance deadline for Part D controlled substance prescriptions written for beneficiaries in long-term care (LTC) facilities, excluding beneficiaries who are residents of nursing facilities and whose care is provided under Part A of the benefit, from January 1, 2022 to January 1, 2025

- **Proposed Compliance Threshold**

This section proposes to revise §423.160(a)(5) to specify that 70 percent of all prescribing under Part D for Schedule II, III, IV, and V controlled substances be done electronically per calendar year, excluding from the calculation any prescriptions issued while a prescribe falls within an exception or waiver.

- **Proposed Classes of Exceptions**

This section proposes classes of exceptions for prescriptions issued when the prescriber and dispensing pharmacy are the same entity; cases where prescribers issue only a small number of part d prescriptions;

and cases of recognized emergencies and extraordinary circumstances; d. individuals in hospice and nursing facilities.

Background/Rationale

- **Posed Timeframe for EPCS Adoption**

Since finalizing CY 2021 PFS final rule, CMS has received additional prescriber feedback indicating concern with have to implement the electronic prescribing for controlled substances (EPCS) rapidly. CMS has also learned more about the degree to which prescribers have been adversely affected by the COVID-19 pandemic, and that the PHE and the widespread effects of the pandemic may last longer than we had anticipated last year. CMS wants to ensure that their actions do not have unintended consequences, such as the abrupt discontinuation of prescribers' ability to prescribe controlled substances to vulnerable populations, including Part D beneficiaries who need pain treatment or have SUDs. Additionally, CMS wants to wait for the Department of Justice to make updates to the EPCS requirements which, in turn, will allow prescribes to start conducting EPCS more rapidly and easily.

CMS' intent of the compliance extension is to strike a balance between being responsive to stakeholder concerns surrounding the increased implementation barriers faced by LTC facilities, while at the same time helping ensure that these facilities eventually implement EPCS, due to its benefits.

After considering comments in previous rulemaking, CMS has decided that LTC facilities face additional barriers to EPCS adoption that most prescribers do not face. In addition to the current challenge of having to manage for vulnerable residents during the current COVID-19 pandemic, prescribers who work in LTC facilities or who provide care to residents in LTC facilities face technological barriers that other prescribers do not face. One such barrier is that the NCPDP SCRIPT 2017071 standard lacks appropriate guidance for LTC facilities. NCPDP is currently in the process of adopting specific guidance for LTC facilities within the SCRIPT 2017071 standard, which would allow for willing partners to enable three-way communication between the prescriber, LTC facility, and the pharmacy to bridge any outstanding gaps that impede the adoption of the NCPDP SCRIPT 2017071 standard in the LTC setting.

CMS also understands that some LTC settings/services in rural communities do not have sufficient capabilities to support the NCPDP SCRIPT 2017071 standard. This concern is exacerbated by the fact that based on stakeholder feedback and information in several reports, CMS believe LTC settings often include practitioners and staff serving large numbers of residents across multiple nursing homes. This unique set of circumstances means that some practitioners who primarily practice in suburban or urban areas may have to travel to see residents in rural facilities where there is limited broadband, making EPCS transmission set-ups difficult across LTC facilities. However, CMS believes that as broadband access increases and the impact of pandemic decreases, LTCs should be able to more easily conduct EPCS.

- **Proposed Compliance Threshold**

Section 1860D-4(e)(7)(B)(vi) of SUPPORT Act provides the Secretary may grant an exception for a prescription issued for a drug for which the FDA requires a prescription to contain elements that cannot be in electronic prescribing. However, after reviewing the NCPDP standard implementation guide under, CMS does not believe that there are any such prescriptions under that current standard. The statute provides an example of a drug with REMS that include elements to assure safe use. But based on CMS' review of the

NCPDP standard, all opioids have REMS and, as a result, would fall into the exception if there were one, which would frustrate the purpose of the statute. As a result, CMS declines to propose to adopt this suggested exception.

CMS believes that Part D prescribers should be able to conduct EPCS on 70 percent of their part D controlled-substance prescriptions without being overly burdened or burdening patients. Under 1860D-4(e)(7)(D) of the Act, CMS has the authority to specify appropriate penalties for non-compliance with the EPCS requirement. It follows then that CMS should have the authority to specify a threshold for when they would penalize non-compliance.

CMS would conduct this calculation by examining PDE data at the end of the calendar year and dividing the number of Part D controlled substances that the prescriber e-prescribed by the total number of Part D controlled substance prescriptions the prescriber prescribed.

- **Proposed Classes of Exceptions:**

a. Prescriptions Issued When the Prescriber and Dispensing Pharmacy are the Same Entity;

This exception was initially listed in a 2020 RFI and commenters who discussed this exception were supportive of it, stating it would promote patient safety, workflow efficiency, and health IT performance. Other commenters in the RFI noted that requiring EPCS in this circumstance may create an unwarranted artificial workflow structure. CMS believes this is because the EPCS transactions conducted within an organization are commonly handled by a single database that exists within he organization, and should CMS not grant this exemption, these entities would be required to reconfigure their own processes, rather than leverage their own integrated databases.

b. Cases where Prescribers Issue Only a Small Number of Part D Prescriptions;

Based on comments received in the 2020 RFI and stakeholder feedback CMS received about the EPCS in general, they believe it is appropriate to specify that where a prescriber issues a very low volume of controlled substance prescriptions for Part D drugs, and exception should be available. Specifically, it could be unduly burdensome relative to benefit in terms of improving security of prescriptions for controlled substances. So, for those prescribers who prescribe 100 or fewer Part D controlled substance prescriptions per year, the exception would apply.

Based on feedback, CMS understands EHR companies provide initial electronic prescribing set-up free of charge, provided that the prescribers transmit a minimum number of transactions per year. CMS estimates this amount to be 100 Part D controlled substance transactions per year (on average). In order to do EPCS, prescribers would have to have the capability to e-prescribe more broadly. It is for this reason that CMS weighted the cost of e-prescribing set up in general, even though CMS does not intend to include non-part D prescription of controlled substances in the calculation of whether or not prescribers meet the threshold of 100 Part D controlled substance prescriptions per year.

CMS is proposing to give this exception to individual prescribers, regardless of the size of their practice they belong to. CMS believes this exception will protect small prescribers, should they change their place of employment, or if their place of employment does not offer support for implementing EPCS. CMS also believes that prescribers working under most research protocols would fall under the exception.

CMS proposes to implement this proposal by examining PDE claims as of December 31 of the prior year to determine which prescribers fall within the exception.

c. Cases of Recognized Emergencies and Extraordinary Circumstances;

Proposing two exceptions: 1. At proposed § 423.160(a)(5)(iii), is for prescribers who are prescribing during a recognized emergency, such as a natural disaster, a pandemic, or a similar situation where there is an environmental hazard. To qualify for such exception, this circumstance would have to arise from an emergency, or a disaster declared y a federal, state, or local government entity. CMS would determine whether a prescriber qualifies for hits exception based on whether the prescriber's NCPDP database address is in the geographic area of the emergency or disaster declared by a federal, state, or local government entity.

2. At proposed § 423.160(a)(5)(iv), is for prescribers who request and receive from CMS a waiver, which CMS would grant to prescribers who are facing extraordinary circumstances that prevent them from electronically prescribing a controlled substance to a Part D beneficiary, but who are not in an emergency or disaster area. CMS defines "extraordinary circumstance" to mean a situation, other than an emergency or disaster, outside of the control of a prescriber that prevents the prescriber from electronically prescribing a controlled substance to a Part D beneficiary. To meet the standard for the waiver, prescribers must provide documentation showing the existence of a circumstance beyond their control and that such a circumstance prevents them from conducting EPCS.

d. Individuals in Hospice and Nursing Facilities

The SUPPORT Act asked the Secretary to consider whether individuals under the Part D benefit for which they are enrolled in Medicare Part A hospice benefit should be exempt from the EPCS requirement. After considering this issue, CMS has determined that an exception for a prescription made for an individual enrolled in hospice would be inappropriate for several reasons. In sum, the hospice benefit covers the necessary controlled substances under Part A and B, not Part D. This would cause confusion on the part of the prescriber, therefore there is no exception for hospice facilities because they would not be covered under the ECPS requirement for any prescriptions for Part A and B controlled substances.

CMS sought feedback on a potential exemption for residents of nursing facilities who are dual eligible beneficiaries. The stakeholder and federal partner feedback did not inform CMS of any compelling reasons to include an exemption for prescribers issuing prescriptions for individuals who are residents of nursing facilities and eligible for Medicare and Medicaid benefits. CMS has also seen the severe impact that COVID-19 pandemic has had on nursing facility residents, who are at high risk for infection, serious illness, and death from COVID-19, as well as other infectious disease including bacterial infections and flu. For these reasons CMS declines to propose an exemption for prescribers issuing prescriptions for individuals who are residents of nursing facilities and dual eligible.

CMS proposes with respect to compliance from January 1, 2023 through December 31, 2023, CMS compliance actions will consist of sending letters to prescribers believed to be violating ECPS requirements during that time.

Comments:

CMS seeks comment on the following:

- Whether commenters believe that CMS should maintain the January 1, 2022 compliance date, given the benefits of EPCS, and the feasibility for prescribers to adopt EPCS for Part D prescriptions by January 1, 2023

- The benefits, burdens, and challenges to the approach of extending the deadline, rather than creating an LTC waiver or exception to EPCS adoption.
- CMS is seeking comment on their refusal to adopt the statutorily suggested exception. Also seeking comment on the method and the proposal to make 70 percent the compliance threshold for adherence to the EPCS mandate, and what circumstances would make EPCS not feasible.
- **Proposed Classes of Exceptions:**
    - **a. Prescriptions Issued When the Prescriber and Dispensing Pharmacy are the Same Entity –** Seeking comment on this proposal
    - **b. Cases where Prescribers Issue Only a Small Number of Part D Prescriptions –** Seeking comment on the assumption that the cost of EPCS transaction sis less than the cost of transmitting certain transactions manually, therefore the initial investment to install EPCS equipment and software is likely justified once prescribers transmit more than 100 part D controlled substances per year. CMS also seeks comment on the costs of third party applications with additional identity and security measures for EHRs to meet DEA standards. seeking comment on whether prescribers working under research protocols would fall under this exception. CMS is under the assumption that some PDP and MA-PD plans would be willing to donate the technology and services necessary for prescribers to adopt EPCS specifically for researchers, but they seek comment on this assumption. They also seek comment on their choice to not develop an exception for prescribers working under research protocols.
    - **c. Cases of Recognized Emergencies and Extraordinary Circumstances –** Seeking comment on what other extraordinary circumstances, not listed in the statute may prevent prescribers from being able to conduct EPCS. Seeking comments on the proposed waiver process.
    - **d. Individuals in Hospice and Nursing Facilities** – CMS seeks comment on their decision to decline providing an exception for hospice prescribers.
- The proposal of CMS sending letters to prescribers believed to be violating ECPS requirements from January 1, 2023 through December 31, 2023, including what type of compliance action may be appropriate after the initial period described, including whether any penalties should be phased in over time.

L. Updates to the Quality Payment Program (section IV.)

Proposed Changes

- **Timeline for MVP Implementation**

To give providers sufficient time to prepare or shift to the new participation framework, CMS is proposing to begin transitioning to MVPs in the 2023 MIPS performance year. CMS is also defining MVP Participants to mean individual clinicians, single specialty groups, multispecialty groups, subgroups, and APM entities that are assessed on an MVP for all MIPS performance categories. Beginning in the 2025 performance year, they propose that multispecialty groups would be required to form subgroups in order to report MVPs.

- **Additions to MVP Development Criteria**

CMS is proposing to add the following to the MVP development criteria beginning with the 2022 performance year:

1. MVPs must include at least one outcome measure that is relevant to the MVP topic, so MVP Participants are measured on outcomes that are meaningful to the care they provide.
2. Each MVP that is applicable to more than one clinician specialty should include at least one outcome measure that is relevant to each clinician specialty included.
3. In instances when outcome measures are not available, each MVP must include at least one high priority measure that is relevant to the MVP topic, so MVP Participants are measured on high-priority measures that are meaningful to the care they provide.
4. Allow the inclusion of outcomes-based administrative claims measures within the quality component of an MVP.
5. Each MVP must include at least one high priority measure that is relevant to each clinician specialty included.
6. To be included in an MVP, a qualified clinical data registry (QCDR) measure must be fully tested.

- **MVP Participant Registration**

CMS is proposing that in order to report an MVP, an MVP Participant must register for the MVP between April 1 and November 30 of the performance year. To report CAHPS for MIPS survey associated with an MVP, they propose that a group, subgroup, or APM entity complete their MVP registration by June 30 of the performance year to align with the CAHPS for MIPS Survey registration deadline. Additionally, CMS proposes that an MVP Participant would not be able to submit or make changes to the MVP they select after the close of the registration period (November 30 of the performance year) and would not be allowed to report on an MVP they did not register for.

- **Third Party Intermediary Support for MVP**

CMS proposes to require that QCDRs, Qualified Registries, and Health IT vendors support MVPs relevant to the specialties they support and for subgroup reporting to begin with the 2023 performance year. CMS also proposes requiring that CAHPS for MIPS survey vendors support subgroup reporting and MVPs relevant to the CAHPS for MIPS measure associated with an MVP beginning with the 2023 performance year.

- **Proposed MVPs**

CMS is proposing 7 MVPs for the 2023 performance year aligning with the following clinical topics:

1. Rheumatology
2. Stroke Care and Prevention
3. Heart Disease
4. Chronic Disease Management
5. Emergency Medicine
6. Lower Extremity Joint Repair
7. Anesthesia

- **Adoption of Reporting Requirements for MVP**

CMS proposes the following MVP reporting requirements for all MVP Participants:

  - Foundational layer: MVP Participants would select at the time of MVP Participant registration one population health measure to be calculated on. For the 2023 performance year, CMS expects two population health measures will be available for selection: (1) Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System Program (MIPS) Eligible Clinician Groups (finalized in CY 2021 final rule) and (2) Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (proposed). MVP participants would report on the same Promoting Interoperability measures required under traditional MIPS unless they qualified for automatic reweighting or was approved a hardship exception.
  - Quality Performance Category: MVP Participants would select 4 quality measures available. One measure must be an outcome measure (or a high-priority measure if an outcome isn't available or applicable).
  - Improvement Activities Category: MVP Participants would select 2 medium-weighted improvement activities **OR** one high-weighted improvement activity **OR** IA_PCMH, if available in the MVP.
  - Cost Performance Category: CMS would calculate performance exclusively on the cost measures that are included in the MVP using administrative claims data.

- **Updates to Subgroup Reporting for MVPs**

CMS is proposing to establish a subgroup reporting to provide patients and providers, which will be voluntary for the 2023 and 2024 performance years. For the first years of subgroup implementation, CMS proposes to limit subgroup reporting only to clinicians reporting through MVPs or APP. Voluntary reporters, opt-in eligible clinicians, and virtual groups would not be able to report to MIPS through an MVP for the 2023 performance year, due to implementation challenges.

- **Scoring MVPs**

CMS proposes that MVP scoring policies would align with those used in traditional MIPS across all performance categories, with few exceptions noted below. Performance category weights would be consistent with traditional MIPS performance category weights. Reweighting policies for the redistribution of category weights would also align with traditional MIPS, with the exception that they would not reweight the quality performance category if they cannot calculate a score for the MIPS eligible clinician because there is not at least one quality measure applicable and available to the clinician. They also propose to update the scoring hierarchy to include subgroups. This would mean that a MIPS eligible clinician would receive the highest final score that can be attributed to their TIN/NPI combination from any reporting option (traditional MIPS, APM Performance Pathway (APP) reporting, or MVP reporting) and participation option (as an individual, group, subgroup, or APM Entity) except for virtual groups.

- **Performance Feedback and Public Reporting for MVP Participants**

CMS proposes to provide comparative performance feedback within the annual performance feedback to show the performance of like clinicians who report on the same MVP. They are also proposing to delay public reporting of new improvement activities and Promoting Interoperability measures and attestations reported via MVPs by one year. They propose to begin publicly reporting sub-group level performance information beginning with PY 2024 and to create a separate subgroup workflow that would allow subgroup performance information to be publicly reported in an online location that can be navigated to from an individual clinician or group profile page. Lastly, CMS proposes that subgroup scores be publicly reported separately from group scores.

- **APM Performance Pathway Proposals**

CMS proposes to allow MIPS eligible clinicians to report the APP as a subgroup beginning with the 2023 performance year. The definition of a subgroup and eligibility to participate as a subgroup are the same for MVP and APP reporting. Subgroups would not be required to register for reporting the APP.

- **MIPS Eligible Clinician Definition**

CMS proposes to revise the definition of a MIPS eligible clinician to include clinical social workers and certified nurse mid-wives. They have also proposed to automatically reweight the Promoting Interoperability performance category to zero percent for clinical social workers.

- **Performance Threshold Proposals**

CMS proposes to establish the performance threshold using the mean final score from the 2017 performance year/2019 MIPS payment year, which would result in a performance threshold of 75 points. The additional performance threshold would be established at 89 points.

- **Performance Category Weights**

For the 2022 performance year/2024 payment year, the performance category weights are:

  - 30% for the quality performance category.
  - 30% for the cost performance category.
  - 15% for the improvement activities performance category.
  - 25% for the Promoting Interoperability performance category.

- **Changes to Quality Performance Category:**

CMS is proposing the following for the quality performance category:

1. Update quality measure scoring to remove end-to-end electronic reporting and high-priority measure bonus points as well as the 3-point floor for scoring measures
2. Use performance period benchmarks, or a different baseline period for scoring quality measures in the 2022 performance period.
3. Extend the CMS Web Interface as a quality reporting option for registered groups, virtual groups, or other APM Entities for the 2022 performance period.
4. Update the quality measure inventory (a total of 195 proposed for the 2022 performance period).

5. Increase the data completeness requirement to 80% beginning with the 2023 performance period.

- **Changes to the Cost Performance Category**

CMS is proposing to add 5 new episode-based cost measures: 2 procedural measures, 1 acute inpatient measure, and 2 chronic condition measures.

- **Changes to the Improvement Activities Performance Category**

CMS is proposing the addition of 7 new improvement activities, 3 of which are related to promoting health equity. They are also proposing to modify 15 current improvement activities, 11 of which address health equity. Lastly, they are proposing to remove 6 previously adopted improvement activities.

- **Promoting Interoperability Performance Category**

CMS proposes to apply automatic reweighting to clinical social workers and small practices as well as revise reporting requirements and require MIPS eligible clinicians to report the following 2 measures: (1) immunization registry reporting and (2) electronic case reporting. They are also proposing to modify the Provide Patients Electronic Access to Their Health Information measure to require patient health information to remain available to the patient (or patient-authorized representative) to access indefinitely, starting with a date of service of January 1, 2016. Lastly, they are proposing a new measure where MIPS eligible clinicians must attest to conducting an annual assessment of the High Priority Guide of the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) and to modify the Prevention of Information Blocking attestation statements required by eligible clinicians.

- **Public Reporting on Care Compare**

CMS proposes to add affiliations of the following facility types on Care Compare:

1. Long-Term Care Hospitals
2. Inpatient Rehabilitation Facilities
3. Inpatient Psychiatric Facilities
4. Skilled Nursing Facilities
5. Home Health Agencies
6. Hospice
7. End-Stage Renal Disease (ESRD) Facilities

Background/Rationale

- **Timeline for MVP Implementation**

CMS notes the delayed timeline is to provide practices the time they need to review requirements, update workflows, and prepare their systems as needed to report MVPs.

- **Additions to MVP Development Criteria**

CMS notes they recognize that the transition to MVPs will take time and will continue to evaluate the readiness of providers in making the transition while balancing their interest in improving measurement

and making MIPS more focused on value. They believe it is important to provide clarity in their expectations of the number of quality measures and improvement activities that are available for an MVP participant to choose from.

- **Proposed MVPs**

CMS notes that each MVP includes complementary measures and activities and supports patient-centered care and a continued emphasis on the importance of patient outcomes, population health, health equity (including measures and activities that assess health disparities and socioeconomic factors), interoperability, and reduced reporting burden for clinicians.

- **Updates to Subgroup Reporting**

CMS highlights that they heard from patients, clinicians, and other stakeholders that they would like more comprehensive and granular reporting from the MIPS program. To that end, they are proposing to establish subgroup reporting to provide patients and clinicians with information that is clinically meaningful at a more granular level.

- **Scoring MVPs**

CMS believes that proposing to include subgroups in the scoring hierarchy would allow for meaningful data collection and assessment under MVPs, while applying their existing policy of allowing clinicians to receive the highest final score and payment adjustment that can be attributed to them.

- **Performance Feedback and Public Reporting for MVP Participants**

CMS notes that these proposed policies aim to provide meaningful feedback to MVP participants, give MIPS eligible clinicians time to familiarize themselves with MVPs and subgroup reporting, align with the historical approach to report performance information at the level that it is submitted, and to align with subgroup reporting policies.

- **MIPS Eligible Clinician Definition**

CMS believes the revised definition aligns with the APM eligible clinician definition and are responsive to stakeholder requests to be included in the program. They note that both the clinical social workers and certified nurse mid-wives will have an appropriate level of quality measures to report in performance year 2022, including a Clinical Social Worker Specialty Measure Set. Improvement activities for both clinician types will be applicable and available.

- **Performance Threshold Proposals**

The Bipartisan Budget Act of 2018 requires a "gradual and incremental transition" for raising the performance threshold during the first 5 years of the MIPS program. The goal is to reach a performance threshold of "mean or median of the composite performance scores for all MIPS eligible professionals" in Year 6, which is the 2022 performance year/2024 payment year. The statute requires that an additional performance threshold be set at (1) the 25th percentile of the range of possible final scores above the performance threshold or (2) the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold with respect to a prior period.

- **Performance Category Weights**

The performance category weights are specified in statute, and were codified in prior rulemaking, and therefore are not proposals available for comment.

- **Changes to Quality Performance Category**

CMS believes these proposals will help them to move away from the policies established for the transitional period of MIPS and towards a more simplified scoring standard focused on measure achievement. They also anticipate seeing fewer submissions for the 2020 performance period because of the flexibilities they offered due to the COVID-19 Public Health Emergency (PHE).

Comments:

CMS is seeking comments on the following:

- The timeline to sunset traditional MIPS in the future and to eventually make MVP reporting mandatory.
- Whether voluntary reporters, opt-in clinicians, and virtual groups should be allowed to report MVPs in the future.
- The proposed process of cost measure development by stakeholders. Specifically, they are seeking comments on the proposed measure prioritization criteria, priority areas for future episode-based measure development, standards for measure construction and measure components, as well as the challenges that stakeholders may encounter in the development of cost measures. They are also seeking comments on additional circumstances which may limit their ability to reliably calculate cost measure scores that adequately capture and reflect performance (such as due to external factors beyond the control of MIPS clinicians and groups), and which may inform their decision to reweight the cost performance category to provide scoring flexibility in the future.
- The appropriate number of procedures done, or conditions treated at one of the facility types on Care Compare to link from the clinician profile page to the facility page.

M. Regulatory Impact Analysis (section VII.)

Proposed Changes

- **Proposed Change to Conversion Factor (CF) and RVUs for CY 2022**

Conversation Factor (see Table 121 below):

- CMS estimates the CY 2022 PFS CF to be 33.5848 which reflects the budget neutrality adjustment, the 0.00 percent update adjustment factor, and the expiration of the 3.75 percent increase for services furnished in CY 2021, as provided in the CAA. As displayed in the table, the conversion factor for CY 2022 is approximately 1.3083 lower than CY 2021, which generally means a reduction in reimbursement across a wide range of Medicare services.

TABLE 121: Calculation of the CY 2022 PFS Conversion Factor

CY 2021 Conversion Factor		34.8931
Conversion Factor without CY 2021 Consolidated Appropriations Act Provision		33.6319
Statutory Update Factor	0.00 percent (1.0000)	
CY 2022 RVU Budget Neutrality Adjustment	-0.14 percent (0.9986)	
CY 2022 Conversion Factor		**33.5848**

RVUs: Table 123 (CY 2022 PFS Estimated Impact on Total Allowed Charges by Specialty) on page 1181 of the proposed rule summarizes the impact of Work, PE, and MP RVU changes on total allowed charges across specialties. The combined impact of all RVU changes across specialties with respect to Medicare spending is 0%.

Note, the changes per specialty are typically driven by the valuation of a relatively small number of new or potentially misvalued codes and therefore the impact of the RVU change is not uniform across the specialty – as explained, Table 123 percentage changes are based upon aggregated estimated PFS allowed charges summed across all services furnished by Medicare providers within a specialty compared to previous CY. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under "downloads" on the CY 2022 PFS proposed rule website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.