Summary of 2022 Changes to the Medicare Physician Fee Schedule, Quality Payment Program, and Other Federal Programs

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Updates to the Physician Fee Schedule

Introduction

On July 13, 2021, the Centers for Medicare & Medicaid Services (CMS) published the Proposed Rule for the Medicare Physician Fee Schedule (PFS) and the Quality Payment Program (QPP) for Calendar Year (CY) 2022. The Proposed Rule updates payment rates and policies for services supplied under the PFS on or after January 1, 2022. You may access the CMS press release for more information and links to relevant fact sheets. As used throughout this document, “proposed” refers to matters which are scheduled to be implemented in the 2022 payment year but could change following review and comment by the public. This can be compared to “finalized” which refers to matters that will go into effect in 2022 and are not currently subject to change.

Regulatory Impact Analysis (CMS)

For CY 2022, CMS has proposed a conversion factor of $33.58 ($33.5848). This represents a decrease of $1.31 (or 3.75 percent) when compared to the 2021 conversion factor of $34.89 ($34.8931). The proposed decrease is based on several different factors. In CY 2021, Congress passed the Consolidated Appropriations Act of 2021 (CAA), which provided a 3.75 percent increase in the PFS conversion factor for CY21 only. This increase was intended to offset the 10.20 percent PFS conversion factor decrease CMS had finalized and was only funded for CY21. Congress will need to act to extend the update through CY22. The proposed decrease is also a result of the 0 percent update scheduled for the PFS in CY22, which was established by the Medicare Access and CHIP Reauthorization Act of 2015. This table shows the overall estimated impact on total allowed changes for internal medicine and its subspecialities. The table additionally details the specialty impact inclusive and exclusive of congressional action to extend the update to the conversion factor through CY22.

Payment and Documentation Proposals for Evaluation and Management (E/M) Services

CMS is currently reviewing the payment for E/M visit code sets. For CY22, the Agency is making various narrow proposals that consider the recent changes to E/M visit codes and refine some aspects of the E/M visit code set.

Refinements to “Split” or “Shared” E/M Visits
For CY22, CMS has proposed changes to “split” or “shared” E/M visits to better reflect the current practice of medicine, the evolving role of non-physician practitioners (NPPs) as members of the medical team, and to clarify conditions of payment that must be met to bill Medicare for these services. CMS has proposed to define “split visits” as those provided in the facility setting by a clinician and an NPP in the same group. The clinician who conducts more than half (or the substantive portion of) the visit would bill for it. Overlapping time would only

be counted once. The Proposed Rule includes a list of activities where time spent performing can be counted, regardless of whether they involve direct patient contact:

- Preparing to see the patient (e.g., review of tests);
- Obtaining and/or reviewing separately obtained history;
- Performing a medically appropriate examination and/or evaluation;
- Counseling and educating the patient/family/caregiver;
- Ordering medications, tests, or procedures;
- Referring and communicating with other health care professionals (when not separately reported);
- Documenting clinical information in the electronic (or other) health record;
- Independently interpreting results (not separately reported) and communicating results to the patient/family/caregiver; and
- Care coordination (not separately reported).

On the other hand, clinicians and practitioners would not be permitted to count time spent on the following:

- The performance of other services that are reported separately;
- Travel; and
- Teaching that is general and not limited to discussion that is required for the management of a specific patient.

CMS is seeking comment on whether there should be a different list of qualifying activities for determining total time and the substantive portion of split visits provided in emergency departments. The Agency is also soliciting feedback on how “in the same group” should be defined as used in the proposed definition for split (or shared) visits.

The Agency additionally clarified split visits could be reported for new and established patients, initial and subsequent visits, and prolonged services and critical care services. Split visits could also be performed in any institutional setting, including skilled nursing facilities (SNFs) and nursing facilities (unless otherwise prohibited by applicable law or regulation). In reporting these split (or shared) visits, CMS is proposing a modifier will need to be reported to help ensure program integrity – and there must be documentation in the medical record to identify the two individuals who performed the visit.

**Critical Care Services**

Under the Proposed Rule, the definition of “critical care services” would follow the CPT guidebook language for the critical care visit codes. Below is a list of additional proposals by CMS in this area.

- Critical care services furnished by a single clinician or NPP or by more than one practitioner in the same group with the same specialty are reported with CPT code 99291 for the first 30-74 minutes of services provided to a patient on a given date and CPT code 99292 for additional 30-minute increments provided to the same patient. This
represents a change from current CMS policy, which requires a single clinician or NPP to perform the initial 30-74 minutes of critical care services each day.

- Critical care services can be furnished concurrently to the same patient on the same day by more than one practitioner representing more than one specialty, regardless of their group.
- Critical care services can be furnished as split (or shared) visits. The list of activities that can count toward total time spent for purposes of determining the substantive portion for split visits will incorporate the activities in CPT codes 99291 and 99292.
- CMS rejects the CPT rule that critical care and other E/M visits may be furnished to the same patient on the same date by the same clinician and would not allow other E/M visits to be billed for the same patient on the same date as a critical care service when the services are furnished by the same practitioners, or by practitioners in the same specialty and same group to account for overlapping resource costs. CMS is requesting comments on whether this is the right approach.
- Critical care visits cannot be reported during the same time period as a procedure with a global surgical period.

Teaching Physician Services and Primary Care Exception Flexibilities
Following the 2021 changes to coding for office/outpatient E/M visits that permit the clinician to select the visit level based either on medical decision making (MDM) or total time, questions were raised about how teaching physicians who involve residents in furnishing care should consider time spent by the resident in selecting the appropriate E/M level. Currently, if a resident participates in a service furnished in a teaching setting, a teaching physician can bill for the service only if they are present for the key or critical portion of the service. However, under the “primary care exception” to this policy, the teaching physician can bill in certain teaching hospital primary care centers for certain services furnished by a resident without the physical presence of a teaching physician.

In the Proposed Rule, CMS proposes that the time when the teaching physician was present can be included when determining the E/M visit level. However, for services furnished pursuant to the primary care exception, only MDM can be used to select the E/M visit level. CMS is seeking feedback on its assumption that MDM is a more accurate indicator of the appropriate level of the visit relative to time in the context of the primary care exception for services furnished by residents and billed by teaching physicians in primary care centers. CMS is also seeking comments on whether time is an accurate indicator of the complexity of the visit and how teaching physicians might select an office/outpatient E/M visit level using time when directing the care of a patient that is being furnished by a resident in the context of the primary care exception. After expiration of the PHE, office/outpatient levels 4-5 will no longer be included in the primary care exception.

Valuation of Specific Codes
For CY22, the RVS Update Committee (RUC) resurveyed the Chronic Care Management (CCM) code family, including Complex Chronic Care Management (CCCM) and Principal Care Management (PCM), and added five new CPT Codes.

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 (CCM, CCCM, or PCM), who furnishes the care (clinical staff or the physician or NPP), and the time allocated for the services.

CMS reviewed the RUC-recommended values for the 10 codes in the CCM family and is proposing to accept the recommended work values for the codes. CMS believes that proposing to accept these updated values is consistent with the goals of ensuring continued and consistent access to these crucial care management services and acknowledges the Agency’s longstanding concern about undervaluation of care management under the PFS.

CMS is seeking comment, however, on whether keeping professional PCM and CCM at the same value creates an incentive to bill CCM instead of billing PCM when appropriate.

In addition to the proposals on the values for CCM codes, CMS is interested in understanding more about the standard practice used by clinicians to obtain beneficiary consent for these services. During the PHE for COVID-19, CMS allowed stakeholders to obtain beneficiary consent for certain services under general supervision. Before the PHE for COVID-19, CMS required that beneficiary consent be obtained either by or under the direct supervision of the primary care physician.

Table 1: CY22 CCM/CCCM/PCM Proposed Values

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Short Descriptor</th>
<th>Current Work RVU</th>
<th>RUC-Recommended Work RVU</th>
<th>CMS Proposed Work RVU</th>
</tr>
</thead>
<tbody>
<tr>
<td>99439</td>
<td>CCM clinical staff each add 20 min</td>
<td>0.54</td>
<td>0.70</td>
<td>0.70</td>
</tr>
<tr>
<td>99490</td>
<td>CCM clinical staff first 20 min</td>
<td>0.61</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>99491</td>
<td>CCM physician or NPP work first 30 min</td>
<td>1.45</td>
<td>1.50</td>
<td>1.50</td>
</tr>
<tr>
<td>99X21</td>
<td>CCM physician or NPP work each add 30 min</td>
<td>New</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>99487</td>
<td>CCCM clinical staff first 60 min</td>
<td>1.00</td>
<td>1.81</td>
<td>1.81</td>
</tr>
<tr>
<td>99489</td>
<td>CCCM clinical staff each add 30 min</td>
<td>0.50</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>99X22 (currently G2064)</td>
<td>PCM physician or NPP work first 30 min</td>
<td>New</td>
<td>1.45</td>
<td>1.45</td>
</tr>
</tbody>
</table>
If finalized, this will mean an increase in the work RVUs for each of the existing CCM codes and one of the two PCM codes, which will be converting from HCPCS codes to CPT codes.

**Telehealth**

*Permanent Additions to the Medicare Telehealth Services List*

CMS did not propose any permanent additions to the Medicare telehealth services list for CY22. To be added to the telehealth services list, stakeholders must nominate codes they feel meet the criteria to be permanently added under Categories 1 or 2. The criterion for Category 1 is that the requested services are similar to services already on the telehealth list, and the criterion under Category 2 is that there is evidence of clinical benefit if provided as telehealth. CMS declined to add most of the nominated services on the basis that: (1) they were therapeutic in nature and in many instances involve direct physical contact between the clinician and the patient; (2) there was insufficient detail to determine whether all of the necessary elements of the service could be furnished remotely; and (3) there remained a question of whether the objective outcomes for telehealth patients were similar to those of patients receiving the services in-person. Table 2 (based on Table 8 of the Proposed Rule) contains a list of services which were requested but are not proposed for permanent addition:

<table>
<thead>
<tr>
<th>Service Type</th>
<th>HCPCS</th>
<th>Long Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Urodynamics</strong></td>
<td>51741</td>
<td>Complex uroflowmetry (e.g., calibrated electronic equipment)</td>
</tr>
<tr>
<td><strong>Biofeedback</strong></td>
<td>90901</td>
<td>Biofeedback training by any modality</td>
</tr>
<tr>
<td></td>
<td>90912</td>
<td>Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient</td>
</tr>
<tr>
<td></td>
<td>90913</td>
<td>Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td><strong>Neurological &amp; Psychological Testing</strong></td>
<td>96130</td>
<td>Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>96131</td>
<td>Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)</td>
<td></td>
</tr>
<tr>
<td>96132</td>
<td>Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour</td>
<td></td>
</tr>
<tr>
<td>96133</td>
<td>Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)</td>
<td></td>
</tr>
<tr>
<td>96136</td>
<td>Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes</td>
<td></td>
</tr>
<tr>
<td>96137</td>
<td>Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)</td>
<td></td>
</tr>
<tr>
<td>96138</td>
<td>Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes</td>
<td></td>
</tr>
<tr>
<td>96139</td>
<td>Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)</td>
<td></td>
</tr>
<tr>
<td>97110</td>
<td>Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility</td>
<td></td>
</tr>
<tr>
<td>97112</td>
<td>Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities</td>
<td></td>
</tr>
<tr>
<td>97116</td>
<td>Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)</td>
<td></td>
</tr>
<tr>
<td>97150</td>
<td>Therapeutic procedure(s), group (2 or more individuals)</td>
<td></td>
</tr>
<tr>
<td>97161</td>
<td>Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using</td>
<td></td>
</tr>
</tbody>
</table>
standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.

| 97162 | Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family. |

| 97163 | Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family. |

| 97164 | Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family. |

**Therapy Procedures**

| 97530 | Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes |

**Therapy Personal Care**

| 97535 | Self-care/home management training (e.g., activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes |

| 97537 | Community/work reintegration training (e.g., shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes |

| 97542 | Wheelchair management (e.g., assessment, fitting, training), each 15 minutes |

**Therapy Tests and Measurements**

| 97750 | Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes |

| 97755 | Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes |
### Personal Care

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>97763</td>
<td>Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>98960</td>
<td>Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient</td>
</tr>
<tr>
<td>98961</td>
<td>Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 2-4 patients</td>
</tr>
<tr>
<td>98962</td>
<td>Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients</td>
</tr>
</tbody>
</table>

### Evaluative and Therapeutic Services

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>92607</td>
<td>Evaluation for prescription for speech-generating augmentative and alternative communication device, face-to-face with the patient; first hour</td>
</tr>
<tr>
<td>92608</td>
<td>Evaluation for prescription for speech-generating augmentative and alternative communication device, face-to-face with the patient; each additional 30 minutes (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>92609</td>
<td>Therapeutic services for the use of speech-generating device, including programming and modification</td>
</tr>
</tbody>
</table>

**Temporary Additions to the Medicare Telehealth Services List**

In the CY21 PFS Final Rule, CMS created a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis following the end of the PHE. Category 3 describes those services that were added to the Medicare telehealth services list during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under Categories 1 or 2. The CY21 Final Rule provided coverage through the end of the PHE for more than 100 services. Services that were temporarily added on an interim basis would not be continued after expiration of the PHE. In the Proposed Rule, CMS is proposing to retain all services added to the Medicare telehealth services list on a temporary, Category 3 basis, and that were maintained on that list in the CY21 Final Rule, until the end of CY 2023. The Agency believes this will allow additional time for stakeholders to collect, analyze, and submit data to support permanent inclusion on a Category 1 or 2 basis.

**Codes Not Granted Category 3 Status**

Certain codes were added to the Medicare telehealth services list on an interim basis in 2020 but were not granted Category 3 status in the CY21 PFS Final Rule. In the Proposed Rule, CMS solicits comment on whether these codes should be granted Category 3 status. Table 3 (based on Table 11 of the Proposed Rule) contains a list of services which were not included on the telehealth services list on a Category 3 basis:
Table 3: Services Added to Medicare Telehealth Services List for the Duration of the PHE for COVID-19 but were not Added to the Medicare Telehealth Services List on a Category 3 Basis

<table>
<thead>
<tr>
<th>Code Family</th>
<th>HCPCS</th>
<th>Long Descriptor</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Inpatient Services</td>
<td>99221</td>
<td>Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit.</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>99222</td>
<td>Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>99223</td>
<td>Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit.</td>
<td>2</td>
</tr>
<tr>
<td>Observation Care Services</td>
<td>99218</td>
<td>Initial observation care, per day, for the evaluation and management of a patient which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital &quot;observation status&quot; are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit.</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>99219</td>
<td>Initial observation care, per day, for the evaluation and management of a patient which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient</td>
<td>2</td>
</tr>
</tbody>
</table>
hospital "observation status" are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99220</td>
<td>Initial observation care, per day, for the evaluation and management of a patient which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital &quot;observation status&quot; are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit.</td>
</tr>
<tr>
<td>99234</td>
<td>Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of low severity. Typically, 40 minutes are spent at the bedside and on the patient's hospital floor or unit.</td>
</tr>
<tr>
<td>99235</td>
<td>Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.</td>
</tr>
<tr>
<td>99236</td>
<td>Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of high severity. Typically, 55 minutes are spent at the bedside and on the patient's hospital floor or unit.</td>
</tr>
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</table>

**Nursing Facility Services**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99304</td>
<td>Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Typically, 40 minutes are spent at the bedside and on the patient's hospital floor or unit.</td>
</tr>
</tbody>
</table>
agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 25 minutes are spent at the bedside and on the patient's facility floor or unit.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>99305</td>
<td>Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 45 minutes are spent at the bedside and on the patient's facility floor or unit.</td>
</tr>
<tr>
<td>99306</td>
<td>Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 60 minutes are spent at the bedside and on the patient's facility floor or unit.</td>
</tr>
<tr>
<td>99324</td>
<td>Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low severity. Typically, 20 minutes are spent with the patient and/or family or caregiver.</td>
</tr>
<tr>
<td>99325</td>
<td>Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent with the patient and/or family or caregiver.</td>
</tr>
<tr>
<td>99326</td>
<td>Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity.</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<td>--------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>99237</td>
<td>Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent with the patient and/or family or caregiver.</td>
</tr>
<tr>
<td>99238</td>
<td>Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent with the patient and/or family or caregiver.</td>
</tr>
<tr>
<td>G9685</td>
<td>Physician service or other qualified health care professional for the evaluation and management of a beneficiary's acute change in condition in a nursing facility. This service is for a demonstration project</td>
</tr>
<tr>
<td><strong>Home Services</strong></td>
<td></td>
</tr>
<tr>
<td>99341</td>
<td>Home visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.</td>
</tr>
<tr>
<td>99342</td>
<td>Home visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.</td>
</tr>
<tr>
<td>99343</td>
<td>Home visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs.</td>
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</tbody>
</table>
Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.

Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family’s needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.

Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent face-to-face with the patient and/or family.

**Office/Outpatient Services**

99441 Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion.

99442 Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion.

99443 Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion.

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**Treatment of Mental Health Disorders**

The CY22 Proposed Rule includes multiple proposals to expand access to the treatment of mental health disorders. Of particular focus for CMS is addressing the need for increased access to behavioral health services in rural and other underserved areas. These proposals are discussed in greater detail in the following subsections on originating site and audio-only services.
**New Originating Site**

The CAA (2021) included a number of provisions pertaining to Medicare telehealth services. The Medicare telehealth statute at Section 1834(m)(4)(C) of the Act generally limits the scope of telehealth services to those furnished in rural areas and in certain enumerated “originating sites” including clinician offices and hospitals. As required by Section 123(a) of the CAA (amending section 1834(m)(4)(C)(i) of the Act), CMS is broadening the scope of services for which the geographic restrictions do not apply and for which the patient’s home is a permissible originating site to include telehealth services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the end of the PHE. CMS is additionally proposing to amend its regulations to conform with the statutory change of the CAA to include rural emergency hospitals as telehealth originating sites beginning in CY23.

Section 123(a) of the CAA also added a prohibition on payment for a telehealth service furnished in the patient’s home unless the clinician or practitioner furnishes an item or service in-person, without the use of telehealth, within six months prior to the first time the clinician or practitioner furnishes a mental health telehealth service to the beneficiary. This requirement shall not apply to telehealth services furnished for treatment of a diagnosed substance use disorder (SUD) or co-occurring mental health disorder, or to services furnished in an originating site or that meet the geographic requirements specified. In order to implement the new requirement, CMS is proposing that, as a condition of payment, the billing clinician or practitioner must have furnished an in-person, non-telehealth service to the beneficiary within the six-month period before the date of the mental health telehealth service. The Agency is also proposing that this distinction between the telehealth and non-telehealth services must be documented in the patient’s medical record. CMS is seeking comment on whether the required in-person, non-telehealth service could also be furnished by another clinician or practitioner of the same specialty and same subspecialty within the same group as the clinician or practitioner who furnishes the telehealth service. CMS is also seeking comment on whether it would be appropriate to establish a different interval (other than the proposed six months) for these telehealth services when furnished as permitted using audio-only communications technology.

**Payment for Services Using Audio-Only Communication Technology**

In its CY21 Final Rule, CMS specified that the term “telecommunications system” includes two-way, real-time, audio/video communication technology. During the PHE, CMS has used waiver authority to temporarily waive the requirement for use of a telecommunications system that includes video communications technology for certain behavioral health and/or counseling services, and for audio-only E/M visits. Once the PHE ends, emergency waiver authority will no longer be available, and telehealth services will again be subject to all statutory and regulatory requirements.

In the CY22 Proposed Rule, CMS is proposing to revise its definition of “telecommunications system” to permit use of audio-only communications technology for mental health telehealth services under certain conditions when provided to beneficiaries located in their home. While
CMS reiterates its longstanding concerns over program integrity and quality of care, the Agency believes a reassessment of these concerns is reasonable given the now widespread utilization during the PHE of audio-only telehealth services. Based upon an initial review of audio-only telephone E/M claims data collected during the PHE, CMS found audio-only E/M visits have been some of the most performed telehealth services and most were for treatment of a mental health condition. In support of its proposal, CMS cites the possible negative impact on access to care if a sudden discontinuation were allowed, as well as its belief that mental health services are distinct from most other services on the telehealth list in that they do not necessarily require visualization of the patient to fulfill the full scope of service elements.

Regarding this proposal, CMS notes certain conditions must be met. Specifically, the Agency proposes clinicians and practitioners would be required to have the capacity to furnish two-way, audio/video telehealth services, but may provide mental health services via audio-only where the beneficiary is not capable of using or does not consent to the use of two-way, audio/video technology. To monitor utilization and program integrity under the proposed exception, CMS is proposing to create a service-level modifier that would identify these mental health telehealth services furnished in the home using audio-only communications technology. It is proposed that this modifier would also serve to certify the clinician or practitioner had the capability to provide two-way, audio/video technology but instead used audio-only due to beneficiary choice or access limitations.

CMS is seeking comment on all its proposals related to the treatment of mental health disorders. The Agency is also seeking comment on what, if any, additional documentation should be required in the medical record to support the clinical appropriateness of providing audio-only telehealth services for mental health. Additional documentation could include information about the patient’s level of risk and any other guardrails that are appropriate to demonstrate clinical appropriateness and minimize program integrity and patient safety concerns. For purposes of the proposed audio-only mental health services exception, CMS is seeking comment on whether it should exclude certain higher-level services, such as level 4 or 5 E/M visit codes, when furnished alongside add-on codes for psychotherapy.

**Direct Supervision**

In its March 2020 Interim Final Rule with Comment (IFC), CMS changed the definition of “direct supervision” during the PHE to allow the supervising professional to be immediately available through virtual presence using real-time audio/video technology, instead of requiring their physical presence. In the CY21 Final Rule, CMS finalized continuation of this policy through the end of the calendar year in which the PHE ends or December 31, 2021. CMS is seeking comment on whether this flexibility should be continued or potentially be made permanent. The Agency is also seeking comment on:

- The extent to which the flexibility to meet the immediate availability requirement through the use of real-time, audio/video technology is being used during the PHE, and whether clinicians and practitioners anticipate relying on this flexibility after the PHE; and

- The possibility of permanently allowing immediate availability through virtual presence for only a subset of services due to potential concerns over patient safety; and
• Requiring a service level modifier, if this flexibility were made permanent, to identify when the requirements for direct supervision were met using two-way, audio/video communications technology.

**Virtual Check-In Code**

In the CY21 Final Rule, CMS established on an interim basis HCPCS code G2252 (*Brief communication technology-based service, e.g., virtual check-in service, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion*) for an extended virtual check-in. This code could be furnished using any form of synchronous communication technology, including audio-only. In that rule, the Agency finalized a direct crosswalk to CPT code 99442 and established a payment rate of 0.50 work RVUs. In the Proposed Rule, CMS is proposing to permanently adopt coding and payment for CY22, HCPCS code G2252 as described in the CY21 Final Rule.

**Vaccine Administration Services**

Payment rates for Medicare Part B vaccines (influenza, pneumococcal, and hepatitis B [HBV]) have not changed since CY 2019. CMS is seeking feedback on how to update the payment rate for preventive vaccines under Part B.

<table>
<thead>
<tr>
<th>Year</th>
<th>National Payment Rate for G0008, G0009, G0010</th>
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</thead>
<tbody>
<tr>
<td>2015</td>
<td>$25.51</td>
</tr>
<tr>
<td>2016</td>
<td>$25.42</td>
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<tr>
<td>2017</td>
<td>$25.84</td>
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<tr>
<td>2018</td>
<td>$20.88</td>
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<tr>
<td>2019</td>
<td>$16.94</td>
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<tr>
<td>2020</td>
<td>$16.94</td>
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<tr>
<td>2021</td>
<td>$16.94</td>
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</tbody>
</table>

Payment rates for administration of COVID-19 vaccines were separately implemented as part of the CARES Act. Due to the PHE and ongoing interest in payment rates for vaccine administration, CMS is requesting comment to obtain information on the costs involved in furnishing preventive vaccines, with the goal to inform the development of more accurate rates for these services. Specifically, CMS is seeking comment on:

• The different types of health care clinicians (and providers) who furnish vaccines and how those clinicians (and providers) changed since the start of the pandemic;

• How the costs of furnishing flu, pneumococcal, and hepatitis B vaccines compare to the costs of furnishing COVID-19 vaccines, and how costs may vary for different types of clinicians (and providers); and
• How the COVID-19 PHE may have impacted costs and whether clinicians (and providers) envision these costs to continue.

CMS is additionally seeking feedback on its proposed policy to pay $35 add-on for certain vulnerable beneficiaries when they receive a COVID-19 vaccine at home. The Agency is interested in input on what qualifies as the “home” and how it can balance ensuring program integrity with beneficiary access. CMS is also seeking comment on whether they should treat these products the same way it treats other clinician-administered drug and biologicals under Medicare Part B.

Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance

CMS is proposing to add a travel allowance for a lab technician to collect a specimen from homebound and/or non-hospital patients. The Agency is proposing to allow these travel logs to be documented using electronic or paper means. The payment for travel allowance is set to expire once the PHE ends. Additionally, this proposal would also allow labs to perform COVID-19 diagnostic testing to these patients.

Billing for Physician Assistant (PA) Services

In accordance with Section 403 of the CAA, the CY22 Proposed Rule adds Physician Assistants (PA) as authorized to bill and be paid for directly by Medicare for professional services in the same way that Nurse Practitioners (NP) and Clinical Nurse Specialists (CNS) are. Previously, PA services could only be paid to the PA’s employer. This addition will apply to both PAs in rural and non-rural settings.

Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) furnished by Opioid Treatment Programs (OTPs)

CMS is proposing a number of modifications to this section. Specifically, CMS is proposing:
• Geographic adjustments to the non-drug component of the OUD bundled payment (including take-home opioid antagonist medication [Naloxone]);
• Payments for medications delivered, administered, or dispensed to a beneficiary as part of an adjustment to the bundled payment are to be considered a duplicative payment if Part B or D also separately paid for the same medication to the same beneficiary on the same day;
• A new G-Code and payment for a new, higher dose nasal spray Naloxone product; and
• To revise the regulations to allow OTPs to continue to furnish therapy and counseling using audio-only communication technology when audio/video is not available to the beneficiary or the beneficiary has not consented to use. After the PHE ends, OTPs would be required to use the -95 modifier to the counseling and therapy add-on code (G2080).

Updates to Physician Self-Referral Regulations under Stark Law
CMS recently made several changes to the Stark Law regulations, which were effective January 19, 2021. Among the changes finalized, the Agency revised the definition of “indirect compensation arrangement” which added a second condition related to the compensation under review for the compensation to potentially implicate the Stark Law. In the CY22 Proposed Rule, CMS is backtracking this definition. Specifically, CMS is revising the definition to make clear it only applies if the compensation arrangement closest to the clinician involves compensation for that clinician’s (or clinician’s immediate family members’) personally performed services. All other arrangements would be analyzed under essentially the same definition that was in effect prior to January 19, 2021.

CMS is also proposing to define the word “unit “contained in the definition of “indirect compensation arrangement” which was finalized in January 2021. Under the Proposed Rule, “unit” would be defined as: (1) time, where the compensation paid to the clinician (or immediate family member) is based solely on the period of time during which the services are provided; (2) service, where the compensation paid to the clinician (or immediate family member) is based solely on the service provided; or (3) time, where the compensation paid to the physician (or immediate family member) is not based solely on the period of time during which a service is provided or based solely on the service provided.

In connection with the PHE for the COVID-19 pandemic, CMS is additionally proposing revisions to the Stark exception for Preventive Screening Tests, Immunizations, and Vaccines at 42 CFR § 411.355(h). CMS states these changes are to ensure that the way the exception currently reads does not impede the availability of COVID-19 vaccines for Medicare and other patients. The exception currently only excepts referrals for vaccines that are subject to CMS-mandated frequency limits. If finalized, the Proposed Rule would make permanent the exception’s availability for the COVID-19 vaccine even if CMS does not impose the frequency limits for the vaccine.

**Updates to the Open Payments Program**

The Open Payment program is a statutorily mandated program that promotes transparency by providing information to the public about financial relationships between the pharmaceutical and medical device industry, and clinicians. In the Proposed Rule, CMS proposes changes related to the collection of Open Payments data beginning in 2023 for reporting in 2024. These changes include:

- Adding a mandatory payment context field for payments or transfers of value attributed to teaching hospitals;
- Adding the option to recertify annually even when no records are being reported;
- Disallowing record deletions without substantiated reason;
- Updating the definition of ownership and investment interest;
- Adding a definition for a clinician-owned distributorship as a subset of applicable manufacturer and group purchasing organizations;
• Requiring reporting entities to disclose relationships they have with other companies for the purposes of transparent reporting;
• Disallowing publications delays for general payment records;
• Clarifying the exception for short-term loans applies for 90 total days in a calendar year, regardless of whether the 90 days were consecutive; and
• Removing the option to submit and attest to general payment records with an “ownership” Nature of Payment category.

Payment for Principal Care Management (PCM) Services in Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs)

CMS is proposing to allow RHCs and FQHCs to concurrently bill for chronic care management and transitional care management services, administer COVID-19 vaccines, and amend regulations for tribal organizations.

As mentioned in the telehealth section of this summary, CMS is proposing to allow RHCs and FQHCs to act as an originating site for the purposes of providing telehealth services to mental health patients, including audio-only visits. CMS is also implementing a provision of the CAA that requires that independent RHCs and clinician-based RHCs in a hospital with 50 or more beds receive an increase in their payment limit per visit starting April 1, 2021. This increase would be phased-in over an eight-year period (2021-2028), with a specific amount for each year.

Requiring Certain Manufacturers to Report Drug Pricing Information for Part B, and Other Items

CMS is proposing to implement the reporting requirements of Section 401 of the CAA (2021). Section 401 established a requirement that manufacturers without Medicaid drug rebate agreements report quarterly average sales price (ASP) information beginning in January 2022 for drugs and biologics paid for by Part B. A civil monetary penalty of $10,000 per price misrepresentation per day will be issued for the failure to report.

Electronic Prescribing of Controlled Substances (EPCS)

The CY21 PFS Final Rule implemented Section 2003 of the SUPPORT Act mandating electronic prescribing of Schedule II-V controlled substances under Medicare Part D beginning on January 1, 2021. The Final Rule established January 1, 2022, as a compliance date for this requirement. Based on the consideration of challenges brought on by the COVID-19 pandemic, CMS is proposing to extend the compliance date for ECPS requirements until January 1, 2023. The Agency is also proposing to further extend the compliance date for Part D controlled substance prescriptions written for beneficiaries in long-term care facilities until January 1, 2025, due to the unique circumstances of these clinicians.
CMS further proposes that, in order for prescribers to be considered compliant, they must prescribe at least 70 percent of their Part D controlled substance (Schedule II, III, IV, and V) prescriptions electronically per calendar year. Proposed exceptions to this requirement would be for prescriptions issued where the prescriber and dispensing pharmacy are the same entity, prescribers who prescribe 100 or fewer Part D controlled substance prescriptions per year, prescribers who are prescribing during a recognized emergency (e.g., a natural disaster or pandemic), and prescribers who request and receive a waiver from CMS due to extraordinary circumstances. As a means of enforcement, CMS proposes that its compliance actions in CY 2023 would consist of sending letters to prescribers that the Agency believes are violating the EPCS requirement. The Agency notes it will consider whether further compliance actions will be necessary in future rulemaking and is requesting feedback on this method and the proposed threshold.

The Agency requests comments on whether there are any concerns that should be addressed regarding the way the EPCS program is working. CMS is also seeking comment on whether there are any concerns about the cost of implementing and using EPCS.

**Appropriate Use Criteria (AUC) Program for Advanced Diagnostic Imaging**

The Protecting Access to Medicare Act of 2014, Section 218(b), established the Appropriate Use Criteria program. In the CY 2018 PFS Final Rule, CMS established January 1, 2020, as the effective date for the program, with the first year serving as the operations and education testing period. In response to the COVID-19 pandemic, in July 2020, CMS extended the testing period an additional year. Under this program, there are two sets of HCPCS modifiers. The first set is to be included on the same claim line as the G-code. This set identifies the Clinical Decision Support Mechanism (CDSM) consults and reports whether the imaging ordered adheres to the AUC, or if the CDSM does not contain applicable AUC. The second set of modifiers is available for use when the ordering professional does not consult a qualified CDSM.

In the CY22 Proposed Rule, CMS proposes to delay the effective date for the penalty period until January 1, 2023, or January of the year following the end of the PHE, whichever is later. CMS believes this delayed implementation is a proper acknowledgment of the impact of the COVID-19 pandemic and the time required to implement any operational changes to its claim processing and prepare for the upcoming penalty phase.

CMS is seeking comment on whether it is more appropriate to deny or return claims that fail AUC claims processing edits during this period. Specifically, CMS is considering whether claims that do not pass the AUC claims processing edits, and therefore will not be paid, should be initially returned to the health care clinician so they can be corrected and resubmitted, or should be denied so they can be appealed. CMS also requests comment on whether the penalty phase should begin first with returning claims and then transition to denying claims after a period of time. The Agency hopes this feedback will help it better understand which pathway would be most appropriate once the AUC program is fully implemented.
Innovative Technology and Artificial Intelligence (AI) Request for Information

In the Proposed Rule, CMS is soliciting feedback on a variety of questions regarding coverage of AI and other innovative technologies. Among other questions, CMS is looking for feedback on:

- To what extent are innovative technologies like software or AI replacing clinician work?
- How innovative technology such as software algorithms and/or AI is affecting physician work time and intensity of furnishing services involving the use of such technology?
- How is innovative technology such as software algorithms and/or AI changing cost structures in the clinician office setting?
- How is innovative technology affecting beneficiary access to Medicare-covered services?
- Compared to other services paid under the PFS, are services that are driven by or supported by innovative technology, such as software algorithms and/or AI, at greater risk of overutilization or more subject to fraud, waste, or abuse?

Quality Payment Program (QPP)

For Performance Year (PY) 2021, there are two exceptions that may be applied for: extreme and uncontrollable circumstances, and the MIPS Promoting Interoperability (PI) application. Both of these exceptions require an application be received by December 31, 2021, as they are not automatic.

CMS is proposing to extend CMS web interface as a collection type for quality reporting into the 2022/2023 PYs.

MIPS Value Pathway (MVP)

CMS is proposing to begin the MVP program in CY 2023 to provide time for MIPS-eligible clinicians to familiarize themselves with MVPs and begin preparing their practices (e.g., system updates). For the CY23 PY, CMS proposes seven MVPs (Rheumatology, Stroke Care and Prevention, Heart Disease, Chronic Disease Management, Emergency Medicine, Lower Extremity Joint Repair, and Anesthesia).

As an example of the MVP most applicable to internists, MVP for Optimizing Chronic Disease Management beginning in PY 2023 is proposed as follows:

**Quality Measures**

- Q006: Coronary Artery Disease: Antiplatelet Therapy
- Q107: Adult Major Depressive Disorder: Suicide Risk Assessment
- Q118: Coronary Arter Disease: Angiotensin-Converting Enzyme Inhibitor or Angiotensin Receptor Blocker Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)
- Q119: Diabetes: Medical Attention for Nephropathy
- Q236: Controlling High Blood Pressure
Improvement Activities

- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_21: Improved practices that disseminate appropriate self-management materials
- IA_CC_13: Practice improvements for bilateral exchange of patient information
- IA_AHE_3: Promote use of Patient-Reported Outcome Tools
- IA_BE_20: Implementation of condition-specific chronic disease self-management support programs
- IA_BE_22: Improved practices that engage patients pre-visit
- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results
- IA_CC_12: Care coordination agreements that promote improvements in patient tracking across settings
- IA_CC_14: Practice improvements that engage community resources to support patient health goals
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient’s Medical Record
- IA_PCMH: Implementation of Patient-Centered Medical Home model
- IA_PSPA_19: Implementation of formal quality improvement methods, practice changes or other practice improvement processes

Cost

The Total Per Capita Cost is proposed to be the measure that aligns with this MVP, as there are no current episode-based measures. The two new proposed episode-based measures, diabetes and asthma/COPD, could be applicable in future rulemaking.

Promoting Interoperability

The scoring methodology for Promoting Interoperability (PI) in MVPs will be the same as in traditional MIPS, except for subgroups, which will be scored based on their affiliated group’s PI score. As in traditional MIPS, the scoring of the PI category recognizes the importance of using CEHRT to support quality improvement, patient engagement, and interoperability.

PY 2022 MIPS Changes

PY22 Reporting Exemptions Due to COVID-19

In response to the COVID-19 PHE, CMS is granting hardship exemptions on a case-by-case basis. If a clinician submits a hardship exemption application and the application is approved, they will
not be eligible for a bonus or potentially face a penalty based on their MIPS performance in 2021.

**PY22 Scoring and PY21 Performance Feedback**

CMS is proposing to sunset traditional MIPS at the end of the 2027 performance and data submission periods and move to using only MVPs. The Agency notes that MIPS has been criticized as being expensive and time consuming, with low positive payment adjustments as a reward, and an uncertainty regarding its impact on patient care. At the same time, however, CMS raises concern about the proposal to sunset traditional MIPS because MVPs remain untested, and it is unclear whether there will be MVP options for all participants.

CMS is statutorily required to weight the cost and quality performance categories equally, beginning with PY22. For PY22, the proposed MIPS performance category weights are summarized below (compared to PY 2021):

<table>
<thead>
<tr>
<th>Performance Category</th>
<th>PY 2021 Weight</th>
<th>PY 2022 Proposed Weight</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality</td>
<td>40%</td>
<td>30%</td>
<td>-10%</td>
</tr>
<tr>
<td>Cost</td>
<td>20%</td>
<td>30%</td>
<td>+10%</td>
</tr>
<tr>
<td>Promoting Interoperability</td>
<td>25%</td>
<td>25%</td>
<td>0%</td>
</tr>
<tr>
<td>Improvement Activities</td>
<td>15%</td>
<td>15%</td>
<td>0%</td>
</tr>
</tbody>
</table>

**Quality Category**

There are currently 206 quality measures available for the 2021 performance period. CMS is proposing a total of 195 quality measures for the 2022 performance period. A complete list of the new quality measures proposed for the CY 2022 MIPS performance period can be found [here](#).

CMS is proposing to maintain the current data completeness threshold at 70 percent for the 2022 performance period with a proposal to increase the data completeness threshold to 80 percent for the 2023 performance period. This means that to meet the current and CY21 proposed data completeness criteria, a clinician must report performance data (performance met or not met, or denominator exceptions) for at least 70 percent of the denominator eligible encounters.

Beginning with the 2022 performance period, CMS is proposing the following changes to quality measure scoring to align with proposals for scoring MVPs:

- Establish a five-point floor for the first three performance periods for new measures.
- Remove the three-point floor for measures that can be scored against a benchmark.
  - These measures would receive one to 10 points.
  - (Note: This proposal would not apply to new measures in the first two performance periods available for reporting).
• Remove the three-point floor for measures without a benchmark (except small practices of 15 or fewer clinicians)
  o These measures would receive zero points.
  o Small practices would continue to earn three points.
  o (Note: This proposal would not apply to new measures in the first two performance periods available for reporting. This proposal would not apply to administrative claims measures. Measures calculated from administrative claims are excluded from scoring if the case minimum is not met).
• Remove bonus points for reporting additional outcome and high priority measures, beyond the one required.
• Remove bonus points for measures that meet end-to-end electronic reporting criteria.

CMS increased previously established scoring flexibility by:
• Expanding the list of reasons that a quality measure may be impacted during the performance period. For 2022, CMS is further proposing to expand the list of reasons that a quality measure may be impacted to include errors included in the measure specifications as finalized as cause to suppress or truncate a measure.
  o These errors include, but are not limited to:
    ▪ Changes to the active status of codes;
    ▪ The inadvertent omission of codes; and
    ▪ The inclusion of inactive or inaccurate codes.

Promoting Interoperability (PI) Category
CMS is proposing to make several modifications to the PI category. Specifically, CMS is proposing:
• To apply automatic reweighting to clinical social workers and small practices – particularly, reweighting clinical social workers and small practices to zero if they do not report the category, and redistributing its weight to another category or categories;
• To make modifications to the Public Health and Clinical Data Exchange objective to require MIPS-eligible clinicians to report on Immunization Registry Reporting and Electronic Case Reporting;
• Beginning in PY22, MIPS-eligible clinicians would receive 10 points for reporting “yes” to the required measures Immunization Registry Reporting and Electronic Case Reporting (unless a qualified exception applies);
• To add a requirement in the Provide Patients Electronic Access to Their Health Information measure to require patient health information remain available to the patient to access indefinitely (starting with encounters on or after January 1, 2016);
• A new measure where 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 to distinguish this from separate information blocking policies under the Office of the National
Coordinator for Health Information Technology (ONC) requirements established in the 21st Century Cures Act.

CMS is seeking comment on all the proposals included in this subsection. Particularly, CMS is seeking comments on their intention to align additional PI performance category objectives with approaches utilizing HL7 Fast Healthcare Interoperability Resources (FHIR®) standard Release-4 based API functionality, specifically targeting the Health Information Exchange as well as the Public Health and Clinical Data Exchange objectives. CMS is interested in public comments on how these two program objectives could be furthered through the use of FHIR®-based API solutions. The Agency is interested in the following questions:

- To what degree are stakeholders currently using or interested in using APIs to exchange information in support of the numerator/denominator measures under the HIE objective?
- What revisions to the measures under the HIE objective should CMS explore to facilitate use of standards-based APIs in health IT modules certified under the 2015 Edition Cures Update?
- How could technical approaches utilizing the FHIR® standard enhance existing data flows required under the public health measures?
- What are promoting FHIR®-based approaches to public health reporting use cases that the ONC and CMS should explore for potential future consideration as part of the PI performance category and the ONC Health IT Certification Program?
- To what degree are PHAs and individual states currently exploring API-based approaches to conducting public health registry reporting?
- What other factors do stakeholders see as critical factors to adopting FHIR®-based approaches?
- What potential policy and program changes in CMS and other HHS programs could reduce health care clinician and health IT developer burden related to measures under the Health Information Exchange and the Public Health and Clinical Data Exchange objectives?

Improvement Activities (IA) Category

There is currently no existing policy to remove activities outside of the rulemaking process. CMS is proposing that in the case of an IA for which there is a reason to believe that the continued collection raises possible patient safety concerns or is obsolete, the Agency would promptly suspend the IA and immediately notify clinicians and the public through the usual communication channels, such as listservs and Web postings. CMS would then propose to remove or modify the IA as appropriate in the next rulemaking cycle.

Further, CMS is proposing two new criteria for nominating new IAs:

- Shouldn’t duplicate other IAs in the inventory.
- Should drive improvements that go beyond standard clinical practices.

CMS also proposes that new IAs must, at minimum, meet all of the following eight criteria, consisting of the two proposed criteria above and these six existing criteria:
1. Relevance to an existing IAs subcategory (or a proposed new subcategory).
2. Importance of an activity toward achieving improved beneficiary health outcomes.
3. Feasible to implement, recognizing importance in minimizing burden, including, to the extent possible, for small practices, practices in rural areas, or in areas designated as geographic Health Professional Shortage Areas by the Health Resources and Services Administration (HRSA).
4. Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes.
5. Can be linked to existing and related MIPS quality, promoting interoperability, and cost measures, as applicable and feasible.
6. CMS is able to validate the activity.

Finally, the Agency is proposing six optional factors that they may use to consider nominated activities (made up of previously finalized criteria):
   1. Alignment with patient-centered medical homes.
   2. Support for the patient’s family or personal caregiver.
   3. Responds to a PHE as determined by the Secretary.
   4. Addresses improvements in practice to reduce health care disparities.
   5. Focus on meaningful actions from the person and family’s point of view.
   6. Representative of activities that multiple individual MIPS-eligible clinicians or groups could perform (i.e., primary care, specialty care).

Cost Category
CMS is proposing to add five newly developed episode-based cost measures into the MIPS cost performance category beginning with the CY22 performance period.
   • Two procedural measures: Melanoma Resection, Colon and Rectal Resection
   • One acute inpatient measure: Sepsis
   • Two chronic condition measures: Diabetes, Asthma/Chronic Obstructive Pulmonary Disease [COPD]

Within the Cost Measure Development Process, all cost measures are developed by CMS’ measure development contractor. In addition to the current process, CMS is proposing a process of external cost measure development and a call for cost measures beginning in CY2022 for earliest adoption into the MIPS program by the 2024 performance period.

APM Performance Pathway (APP)
CMS is proposing to allow MIPS-eligible clinicians to report the APP as a subgroup beginning with the 2023 PY.

Currently, MIPS APM participants can report the APP as an individual, a group, or APM Entity. CMS is proposing to add subgroups as a participation option for reporting the APP beginning with the 2023 PY.
**Complex Patient Bonus**

Provided that a MIPS-eligible clinician, group, virtual group, or APM entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year using the following formula:

\[
\text{Average hierarchical condition category (HCC) risk score} + (\text{the ratio of your dual eligible patients x 5})
\]

The complex patient bonus cannot exceed 5.0 points, except for the 2020 MIPS performance year/2022 payment year when CMS doubled the bonus to 10 points. Because of the concerns of the direct and indirect effects of the COVID-19 PHE, CMS is proposing to continue doubling the complex patient bonus for the 2021 MIPS performance year/2023 MIPS payment year. These bonus points (capped at 10-points) would be added to the final score.

CMS is also proposing to revise the complex patient bonus beginning with the 2022 MIPS performance year/2024 MIPS payment year by:

- Limiting the bonus to clinicians who have a median or higher value for at least one of the two risk indicators (HCC and dual proportion).
- Updating the formula to standardize the distribution of two risk indicators so that the policy can target clinicians who have a higher share of socially and/or medically complex patients.
- Increasing the bonus to a maximum of 10.0 points.

**Medicare Shared Savings Program (MSSP)**

Shared Savings Program ACOs may currently report the CMS Web Interface measures for PY 2021 only. Per prior rulemaking, beginning in performance year 2022, the CMS Web Interface would be removed as a collection type, moving ACOs to report quality data via the new Clinical Quality Measures collection type. However, CMS is proposing to extend the CMS Web Interface as a collection type for the Quality Payment Program for Shared Savings Program ACOs reporting under the APP by continuing to make the CMS Web Interface available for PYs 2022 and 2023.

CMS is proposing that for PY 2022, ACOs would either report the 10 CMS Web Interface measures or the three eCQMs/MIPS CQMs. Under the APP, all ACOs would administer the CAHPS for MIPS Survey and be scored on two administrative claims-based measures (calculated by CMS).

**Table 4: Measures Included in the Proposed APM Performance Pathway Measure Set**

<table>
<thead>
<tr>
<th>Measure #</th>
<th>Measure Title</th>
<th>Collection Type</th>
<th>Submitter Type</th>
<th>Meaningful Measure Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality ID#: 321</td>
<td>CAHPS for MIPS</td>
<td>CAHPS for MIPS Survey</td>
<td>Third Party Intermediary</td>
<td>Patient’s Experience</td>
</tr>
<tr>
<td>Measure #</td>
<td>Description</td>
<td>Data Source</td>
<td>Data Available</td>
<td>Reports Available</td>
</tr>
<tr>
<td>----------</td>
<td>------------------------------------------------------------------------------</td>
<td>----------------------</td>
<td>----------------</td>
<td>---------------------</td>
</tr>
<tr>
<td># 479</td>
<td>Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups</td>
<td>Administrative Claims</td>
<td>N/A</td>
<td>Admissions &amp; Readmissions</td>
</tr>
<tr>
<td># TBD</td>
<td>Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS</td>
<td>Administrative Claims</td>
<td>N/A</td>
<td>Admissions &amp; Readmissions</td>
</tr>
<tr>
<td># 001</td>
<td>Diabetes: Hemoglobin A1c (HbA1c) Poor Control</td>
<td>eCQM/MIPS CQM/CMS Web Interface*</td>
<td>APM Entity/Third Party Intermediary</td>
<td>Mgt. of Chronic Conditions</td>
</tr>
<tr>
<td># 134</td>
<td>Preventive Care and Screening: Screening for Depression and Follow-up Plan</td>
<td>eCQM/MIPS CQM/CMS Web Interface*</td>
<td>APM Entity/Third Party Intermediary</td>
<td>Treatment of Mental Health</td>
</tr>
<tr>
<td># 236</td>
<td>Controlling High Blood Pressure</td>
<td>eCQM/MIPS CQM/CMS Web Interface*</td>
<td>APM Entity/Third Party Intermediary</td>
<td>Mgt. of Chronic Conditions</td>
</tr>
<tr>
<td># 318</td>
<td>Falls: Screening for Future Fall Risk</td>
<td>CMS Web Interface*</td>
<td>APM Entity/Third Party Intermediary</td>
<td>Preventable Healthcare Harm</td>
</tr>
<tr>
<td># 110</td>
<td>Preventive Care and Screening: Influenza Immunization</td>
<td>CMS Web Interface*</td>
<td>APM Entity/Third Party Intermediary</td>
<td>Preventive Care</td>
</tr>
<tr>
<td># 226</td>
<td>Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention</td>
<td>CMS Web Interface*</td>
<td>APM Entity/Third Party Intermediary</td>
<td>Prevention and Treatment of Opioid and Substance Use Disorders</td>
</tr>
<tr>
<td># 113</td>
<td>Colorectal Cancer Screening</td>
<td>CMS Web Interface*</td>
<td>APM Entity/Third Party Intermediary</td>
<td>Preventive Care</td>
</tr>
<tr>
<td># 112</td>
<td>Breast Cancer Screening</td>
<td>CMS Web Interface*</td>
<td>APM Entity/Third Party Intermediary</td>
<td>Preventive Care</td>
</tr>
<tr>
<td># 438</td>
<td>Statin Therapy for the Prevention and Treatment of Cardiovascular Disease</td>
<td>CMS Web Interface*</td>
<td>APM Entity/Third Party Intermediary</td>
<td>Mgt. of Chronic Conditions</td>
</tr>
</tbody>
</table>
+ Note that Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134) do not have benchmarks and are therefore not scored; they are, however, required to be reported in order to complete the Web Interface dataset. *ACOs will have the option to report via Web Interface for the 2021 MIPS Performance year only.

2022 NOTE: Based on the ACO’s chosen reporting option (Web Interface or the eCQMs/MIPS CQMs), either six or 10 measures (seven CMS Web Interface measures, one CAHPS for MIPS Survey measure, and two administrative claims-based measures) will be included in the calculation of the ACO’s quality performance score.

2023 NOTE: Based on the ACO’s chosen reporting option, either six or 11 measures (eight CMS Web Interface measures, one CAHPS measure, and two claims-based measures) will be included in the calculation of the ACO’s quality.

Coupled with the proposed revisions to the quality reporting requirements for the Shared Savings Program, CMS is proposing to freeze the quality performance standard at the 30th percentile MIPS quality performance category score for PY 2023, as well as providing an incentive for ACOs to report eCQM/MIPS CQM measures in PYs 2022 and 2023.

- For PY 2022, if an ACO reports:
  - The 10 CMS Web Interface measures and achieves a quality performance score equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, the ACO would meet the quality performance standard used to determine shared savings and losses.
  - The three eCQM/MIPS CQM measures (meeting data completeness and case minimum requirements) and achieves a quality performance score equivalent to the 30th percentile benchmark on one measure in the APP measure set, the ACO would meet the quality performance standard used to determine shared savings and losses.

- For PY 2023, if an ACO reports:
  - The 10 CMS Web Interface measures and at least one eCQM/MIPS CQM measure and achieves a quality performance score equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, the ACO would meet the quality performance standard used to determine shared savings and losses.
  - The three eCQMs/MIPS CQM measures (meeting data completeness and case minimum requirements) and achieves a quality performance score equivalent to the 30th percentile benchmark on one measure in the APP measure set, the ACO would meet the quality performance standard used to determine shared savings and losses.
• In PY 2024, the threshold for the quality performance standard will increase to the 40th percentile MIPS Quality performance category score.
• Finally, for PY 2021 and subsequent performance years, we clarify that the CAHPS for MIPS minimum sampling thresholds also apply to Shared Savings Program ACOs.

**Medicare Diabetes Prevention Program (MDPP)**

The MDPP was developed to prevent Medicare enrollees with pre-diabetes from converting into full diabetes. Participating entities give structured, coach-led sessions using a Centers for Disease Control and Prevention (CDC) curriculum to provide training related to diet, exercise, and weight management. During the PHE, CMS waived the fee to participate, resulting in an increase in participation.

Following expiration of the PHE, CMS is proposing to continue the waiver of the enrollment application fee beginning on January 1, 2022. CMS is additionally proposing to increase the performance payments when patients achieve a five percent weight loss goal, as well as proposing changes to beneficiary eligibility after January 1, 2022. These changes are intended to minimize barriers to participation and enhance the program.

**Advancing to Digital Quality Measurement and the Use of FHIR® in Physician Quality Programs – Request for Information**

The Proposed Rule includes a RFI to collect information on planning and transitioning CMS programs to complete digital measurement by 2025. Maintaining alignment with the Department of Health and Human Services (HHS) Health Quality Roadmap, CMS is approaching priorities and initiatives with other entities, like the ONC (i.e., 21st Century Cures Act), to promote data interoperability and access. The RFI seeks comments on the following:

• CMS adoption of FHIR® to reduce the collection and analysis burden imposed by current electronic quality measures. Under the HL7 framework, quality data reporting programs would utilize a standardized data collection structure and single terminology to collect electronic measure data.
• Enhancement of the definition of dQM so that it contains language regarding proposed software that processes digital data to determine measure scores.
• Redesign quality measures as “self-contained tools” that dQM software incorporates end-to-end measure calculation solutions.
• Alignment of quality measure reporting programs across federal and state agencies and other sectors via the adoption of a dQM portfolio.

**Health Equity Initiative – Request for Information**

CMS makes several proposals to advance health equity, consistent with President Biden’s recent Executive Order 13985. The 2022 Proposed Rule includes a RFI asking for feedback on the Agency’s efforts to collect additional data to identify and respond to health disparities in its
programs and policies. The Agency notes several strategies it has considered, including clinician and/or public-facing reports on MIPS quality measures stratified by dual-eligible status, race, and other factors. CMS is also seeking comment on ways the Agency can increase the collection of demographic and social risk data, including the collection of a “minimum set” of demographic elements (e.g., race, ethnicity, language, disability status) that could be used for a variety of tracking and quality measurement purposes. The Agency is considering using EHRs as a data collection mechanism.