DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 414, 424, and 425

[CMS-1676-P]

RIN 0938-AT02

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses changes to the Medicare physician fee schedule (PFS) and other Medicare Part B payment policies.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 11, 2017. (See the SUPPLEMENTARY INFORMATION section of this final rule with comment period for a list of provisions open for comment.)

ADDRESSES: In commenting, please refer to file code CMS-1676-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to www.regulations.gov. Follow the instructions for “submitting a comment.”

2. By regular mail. You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1676-P,
P.O. Box 8016,
Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. **By express or overnight mail.** You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1676-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. **By hand or courier.** If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201
(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT:

Jamie Hermansen, (410) 786-2064, for issues related to the valuation of anesthesia services and any physician payment issues not identified below.

Lindsey Baldwin, (410) 786-1694, and Emily Yoder, (410) 786-1804, for issues related to telehealth services and primary care.

Roberta Epps, (410) 786-4503, for issues related to PAMA section 218(a) policy and transition from traditional X-ray imaging to digital radiography.

Isadora Gil, (410) 786-4532, for issues related to the valuation of cardiovascular services, bone marrow services, surgical respiratory services, dermatological procedures, and payment
rates for nonexcepted items and services furnished by nonexcepted off-campus provider-based departments of a hospital.

Donta Henson, (410) 786-1947, for issues related to ophthalmology services.

Tourette Jackson, (410) 786-4735, for issues related to the valuation of musculoskeletal services, allergy and clinical immunology services, endocrinology services, genital surgical services, nervous system services, INR monitoring services, injections and infusions, and chemotherapy services.

Ann Marshall, (410) 786-3059, for issues related to primary care, chronic care management (CCM), and evaluation and management (E/M) services.

Geri Mondowney, (410) 786-4584, for issues related to malpractice RVUs.

Patrick Sartini, (410) 786-9252, for issues related to the valuation of imaging services and malpractice RVUs.

Michael Soracoe, (410) 786-6312, for issues related to the practice expense methodology, impacts, conversion factor, and valuation of pathology and surgical procedures.

Pamela West, (410) 786-2302, for issues related to therapy services.

Corinne Axelrod, (410) 786-5620, for issues related to rural health clinics or federally qualified health centers.

Felicia Eggleston, (410) 786-9287, for issues related to DME infusion drugs.

Rasheeda Johnson, (410) 786-3434, for issues related to initial data collection and reporting periods for the clinical laboratory fee schedule.

Edmund Kasaitis, (410) 786-0477, for issues related to biosimilars.

JoAnna Baldwin, (410) 786-7205, or Sarah Fulton, (410) 786-2749, for issues related to appropriate use criteria for advanced diagnostic imaging services.
Alesia Hovatter, (410) 786-6861, for issues related to PQRS.

Alexandra Mugge, (410) 786-4457, or Elizabeth Holland, (410) 786-1309, for issues related to the EHR incentive program.

Rabia Khan or Terri Postma, (410) 786-8084 or ACO@cms.hhs.gov, for issues related to the Medicare Shared Savings Program.

Kimberly Spalding Bush, (410) 786-3232, or Fiona Larbi, (410) 786-7224, for issues related to Value-based Payment Modifier and Physician Feedback Program.

Wilbert Agbenyikey, (410) 786-4399, for issues related to MACRA patient relationship categories and codes.

Carlye Burd, (410) 786-1972, or Albert Wesley, (410) 786-4204, for issues related to diabetes prevention program.

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Acronyms
In addition, because of the many organizations and terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

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<tr>
<th>Acronym</th>
<th>Term</th>
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<tbody>
<tr>
<td>A1c</td>
<td>Hemoglobin A1c</td>
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<tr>
<td>AAA</td>
<td>Abdominal aortic aneurysms</td>
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<tr>
<td>ACO</td>
<td>Accountable care organization</td>
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<tr>
<td>AMA</td>
<td>American Medical Association</td>
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<tr>
<td>ASC</td>
<td>Ambulatory surgical center</td>
</tr>
<tr>
<td>ATA</td>
<td>American Telehealth Association</td>
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<tr>
<td>ATRA</td>
<td>American Taxpayer Relief Act (Pub. L. 112-240)</td>
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<tr>
<td>AWV</td>
<td>Annual wellness visit</td>
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<tr>
<td>BBA</td>
<td>Balanced Budget Act of 1997 (Pub. L. 105-33)</td>
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<tr>
<td>BLS</td>
<td>Bureau of Labor Statistics</td>
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<tr>
<td>CAD</td>
<td>Coronary artery disease</td>
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<tr>
<td>CAH</td>
<td>Critical access hospital</td>
</tr>
<tr>
<td>CBSA</td>
<td>Core-Based Statistical Area</td>
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<tr>
<td>CCM</td>
<td>Chronic care management</td>
</tr>
<tr>
<td>CEHRT</td>
<td>Certified EHR technology</td>
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<tr>
<td>CF</td>
<td>Conversion factor</td>
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<tr>
<td>CG-CAHPS</td>
<td>Clinician and Group Consumer Assessment of Healthcare Providers and Systems</td>
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<tr>
<td>CLFS</td>
<td>Clinical Laboratory Fee Schedule</td>
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</table>
CoA  Certificate of Accreditation
CoC  Certificate of Compliance
CoR  Certificate of Registration
CNM  Certified nurse-midwife
CP  Clinical psychologist
CPC  Comprehensive Primary Care
CPEP  Clinical Practice Expert Panel
CPT  [Physicians] Current Procedural Terminology (*CPT codes, descriptions and other data only are copyright 2015 American Medical Association. All rights reserved.*)
CQM  Clinical quality measure
CSW  Clinical social worker
CT  Computed tomography
CW  Certificate of Waiver
CY  Calendar year
DFAR  Defense Federal Acquisition Regulations
DHS  Designated health services
DM  Diabetes mellitus
DSMT  Diabetes self-management training
eCQM  Electronic clinical quality measures
ED  Emergency Department
EHR  Electronic health record
E/M  Evaluation and management
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<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>EMT</td>
<td>Emergency Medical Technician</td>
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<td>EP</td>
<td>Eligible professional</td>
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<td>eRx</td>
<td>Electronic prescribing</td>
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<td>ESRD</td>
<td>End-stage renal disease</td>
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<td>FAR</td>
<td>Federal Acquisition Regulations</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>FFS</td>
<td>Fee-for-service</td>
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<td>FQHC</td>
<td>Federally qualified health center</td>
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<td>FR</td>
<td>Federal Register</td>
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<td>FSHCAA</td>
<td>Federally Supported Health Centers Assistance Act</td>
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<td>GAF</td>
<td>Geographic adjustment factor</td>
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<td>GAO</td>
<td>Government Accountability Office</td>
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<td>GPCI</td>
<td>Geographic practice cost index</td>
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<td>GPO</td>
<td>Group purchasing organization</td>
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<td>GPRO</td>
<td>Group practice reporting option</td>
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<td>GTR</td>
<td>Genetic Testing Registry</td>
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<td>HCPCS</td>
<td>Healthcare Common Procedure Coding System</td>
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<td>HHS</td>
<td>[Department of] Health and Human Services</td>
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<td>HOPD</td>
<td>Hospital outpatient department</td>
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<td>HPSA</td>
<td>Health professional shortage area</td>
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<tr>
<td>IDTF</td>
<td>Independent diagnostic testing facility</td>
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<td>IPPE</td>
<td>Initial preventive physical exam</td>
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<td>IPPS</td>
<td>Inpatient Prospective Payment System</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>IQR</td>
<td>Inpatient Quality Reporting</td>
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<td>ISO</td>
<td>Insurance service office</td>
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<td>IT</td>
<td>Information technology</td>
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<tr>
<td>IWPUT</td>
<td>Intensity of work per unit of time</td>
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<tr>
<td>LCD</td>
<td>Local coverage determination</td>
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<td>MA</td>
<td>Medicare Advantage</td>
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<tr>
<td>MAC</td>
<td>Medicare Administrative Contractor</td>
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<td>MACRA</td>
<td>Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114-10)</td>
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<td>MAP</td>
<td>Measure Applications Partnership</td>
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<td>MAPCP</td>
<td>Multi-payer Advanced Primary Care Practice</td>
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<td>MAV</td>
<td>Measure application validity [process]</td>
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<td>MCP</td>
<td>Monthly capitation payment</td>
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<td>MedPAC</td>
<td>Medicare Payment Advisory Commission</td>
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<td>MEI</td>
<td>Medicare Economic Index</td>
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<td>MFP</td>
<td>Multi-Factor Productivity</td>
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<td>MIPPA</td>
<td>Medicare Improvements for Patients and Providers Act (Pub. L. 110-275)</td>
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<td>MP</td>
<td>Malpractice</td>
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<td>MPPR</td>
<td>Multiple procedure payment reduction</td>
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<td>MRA</td>
<td>Magnetic resonance angiography</td>
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<td>MRI</td>
<td>Magnetic resonance imaging</td>
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<td>MSA</td>
<td>Metropolitan Statistical Areas</td>
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<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<td>--------------</td>
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<tr>
<td>MSPB</td>
<td>Medicare Spending per Beneficiary</td>
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<tr>
<td>MU</td>
<td>Meaningful use</td>
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<tr>
<td>NCD</td>
<td>National coverage determination</td>
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<tr>
<td>NCQDIS</td>
<td>National Coalition of Quality Diagnostic Imaging Services</td>
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<tr>
<td>NP</td>
<td>Nurse practitioner</td>
</tr>
<tr>
<td>NPI</td>
<td>National Provider Identifier</td>
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<tr>
<td>NPP</td>
<td>Nonphysician practitioner</td>
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<tr>
<td>NQS</td>
<td>National Quality Strategy</td>
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<tr>
<td>OACT</td>
<td>CMS’s Office of the Actuary</td>
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<tr>
<td>OBRA '89</td>
<td>Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239)</td>
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<td>OBRA '90</td>
<td>Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508)</td>
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<tr>
<td>OES</td>
<td>Occupational Employment Statistics</td>
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<tr>
<td>OMB</td>
<td>Office of Management and Budget</td>
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<tr>
<td>OPPS</td>
<td>Outpatient prospective payment system</td>
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<td>OT</td>
<td>Occupational therapy</td>
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<tr>
<td>PA</td>
<td>Physician assistant</td>
</tr>
<tr>
<td>PAMPA</td>
<td>Patient Access and Medicare Protection Act (Pub. L. 114-115)</td>
</tr>
<tr>
<td>PC</td>
<td>Professional component</td>
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<tr>
<td>PCIP</td>
<td>Primary Care Incentive Payment</td>
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<tr>
<td>PE</td>
<td>Practice expense</td>
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<tr>
<td>PE/HR</td>
<td>Practice expense per hour</td>
</tr>
<tr>
<td>PEAC</td>
<td>Practice Expense Advisory Committee</td>
</tr>
</tbody>
</table>
PECOS  Provider Enrollment, Chain, and Ownership System
PFS    Physician Fee Schedule
PLI    Professional Liability Insurance
PMA    Premarket approval
PPM    Provider-Performed Microscopy
PQRS   Physician Quality Reporting System
PPIS   Physician Practice Expense Information Survey
PPS    Prospective Payment System
PT     Physical therapy
PT     Proficiency Testing
PT/INR Prothrombin Time/International Normalized Ratio
PY     Performance year
QA     Quality Assessment
QC     Quality Control
QCDR   Qualified clinical data registry
QRUR   Quality and Resources Use Report
RBRVS  Resource-based relative value scale
RFA    Regulatory Flexibility Act
RHC    Rural health clinic
RIA    Regulatory impact analysis
RUC    American Medical Association/Specialty Society Relative Value Scale Update Committee
RUCA   Rural Urban Commuting Area
Addenda Available Only Through the Internet on the CMS Website

The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. Click on the link on the left side of the screen titled, “PFS Federal Regulations Notices” for a chronological list of PFS Federal Register and other related documents. For the CY 2018 PFS Proposed Rule, refer to item CMS-1676-P. Readers with questions related to accessing any of the Addenda or
other supporting documents referenced in this proposed rule and posted on the CMS website identified above should contact Jamie Hermansen at (410) 786-2064.

**CPT (Current Procedural Terminology) Copyright Notice**

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2016 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. **Executive Summary**

A. Purpose

This major proposed rule proposes to revise payment polices under the Medicare PFS and make other policy changes related to Medicare Part B payment, applicable to services furnished in CY 2018. In addition, this proposed rule includes proposals related to payment policy changes that are addressed in section III. of this proposed rule.

1. **Summary of the Major Provisions**

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE); and malpractice (MP) expense; and, that we establish by regulation each year’s payment amounts for all physicians’ services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. In this major proposed rule, we are proposing to establish RVUs for CY 2018 for the PFS, and other Medicare Part B payment policies, to ensure that our payment systems are
updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. In addition, this proposed rule includes discussions and proposals regarding:

- Potentially Misvalued Codes.
- Telehealth Services.
- Establishing Values for New, Revised, and Misvalued Codes.
- Establishing Payment Rates under the PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital
- Evaluation & Management (E/M) Guidelines and Care Management Services
- Care Coordination Services and Payment for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).
- Payment for DME Infusion Drugs.
- Solicitation of Public Comments on Initial Data Collection and Reporting Periods for Clinical Laboratory Fee Schedule.
- Solicitation of Public Comments on Payment for Biosimilar Biological Products under Section 1847A of the Act.
- Appropriate Use Criteria for Advanced Diagnostic Imaging Services.
- Medicare EHR Incentive Program.
- Medicare Shared Savings Program.
- Value-Based Payment Modifier and the Physician Feedback Program.
- MACRA Patient Relationship Categories and Codes.
- Medicare Diabetes Prevention Program.

2. Summary of Costs and Benefits

We have determined that this major proposed rule is economically significant. For a detailed discussion of the economic impacts, see section VI. of this proposed rule.
K. Proposed Changes to the Medicare Diabetes Prevention Program (MDPP) Expanded Model

1. Background

a. Authority for and Establishment of the MDPP Expanded Model

In the November 15, 2016 Federal Register, we issued a final rule to implement aspects of the Medicare Diabetes Prevention Program (MDPP) expanded model (81 FR 80459 through 80475 and 80552 through 80558) as part of the CY 2017 PFS final rule.

Section 1115A(c) of the Act provides the Secretary with the authority to expand, through rulemaking (including implementation on a nationwide basis), the duration and scope of a model that is being tested under section 1115A(b) of the Act if certain determinations specified in the Act are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act. The MDPP expanded model is an expansion of CMS’ Center for Medicare and Medicaid Innovation’s (Innovation Center) Diabetes Prevention Program (DPP) model test under the authority of section 1115A of the Act. The Secretary expanded the DPP model test in duration and scope under the authority of section 1115A(c) of the Act. For further information on the DPP model test, and the associated National DPP administered by the Centers for Disease Control and Prevention (CDC), we refer readers to the CY 2017 PFS final rule and the following websites:  https://Innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/  and  https://www.cdc.gov/diabetes/prevention/index.html .

The aim of the MDPP expanded model is to continue to test a method of prevention of the onset of type 2 diabetes among Medicare beneficiaries with an indication of prediabetes as defined by the MDPP beneficiary eligibility criteria (finalized at §410.79(c)(1)). Services available through the MDPP expanded model are MDPP services furnished in community and health care settings by coaches, such as trained community health workers or health
professionals. We have designated services under the MDPP expanded model to be covered as additional preventive services under Medicare, as defined in section 1861(ddd) of the Act.

For a detailed discussion of the DPP model test and the development of aspects of the MDPP expanded model, we refer readers to the July 15, 2016 MDPP proposed rule ("Proposed Expansion of the Diabetes Prevention Program (DPP) Model") (81 FR 46413 through 46418), and the CY 2017 PFS final rule (81 FR 80459 through 80475).

In the CY 2017 PFS final rule, we responded to and incorporated certain suggestions from the public comments we received that were within the scope of the MDPP proposals presented in the July 15, 2016 MDPP proposed rule. We indicated in that final rule (81 FR 80459) that the MDPP expanded model would be implemented through at least two rounds of rulemaking. In the CY 2017 PFS final rule, we finalized MDPP policies that will enable CDC-recognized organizations to prepare for enrollment, including finalizing the framework for the MDPP expanded model, details of the MDPP expanded model (codified at §410.79(a) and (b)), beneficiary eligibility criteria (codified at §410.79(c) and (d)), supplier eligibility criteria and supplier enrollment requirements (codified at §424.59, proposed in this rule to be redesignated as §424.205). We also identified several issues, including some issues raised by commenters that we deferred to future rulemaking. The proposals in this proposed rule address a number of issues raised by the public in response to the July 15, 2016 MDPP proposed rule. We also are making additional proposals to implement the MDPP expanded model.

b. Summary of Provisions Finalized in the CY 2017 PFS Final Rule

In the CY 2017 PFS final rule (81 FR 80465 through 80468), we finalized the structure of MDPP services. We provided that the MDPP core benefit consists of at least 16 weekly core sessions over months 1 through 6 and at least 6 monthly core maintenance sessions over months.
7 through 12, furnished regardless of weight loss (§410.79(b) and (c)(2)). We also finalized that Medicare will cover ongoing maintenance sessions after the 12-month core set of MDPP services if beneficiaries achieve and maintain the required minimum weight loss of 5 percent. In section III.K.2.b. of this proposed rule, we are proposing to further revise the structure of MDPP services as a 3-year service period, generally contingent upon a beneficiary’s attainment of two performance goals: achievement and maintenance of weight loss and attendance at a certain number of MDPP sessions.

As used in this proposed rule, the term “MDPP services period” refers to the time period in which MDPP services are furnished under the MDPP expanded model over a minimum of 12 consecutive months and a maximum of 36 consecutive months from the date of the first core session the beneficiary attends. We use the term “set of MDPP services” to include the entirety of MDPP services available under the MDPP expanded model, including core sessions, core maintenance sessions, and, subject to paragraph §410.79(c)(3), ongoing maintenance sessions offered over the course of the MDPP services period. For purposes of this proposed rule and the expanded model, MDPP services would be covered under the “additional preventive services” benefit category under section 1861(ddd)(1) of the Act and paid through the Medicare Part B Trust Fund. As indicated in the CY 2017 PFS, we intended to begin supplier enrollment before MDPP services became available, and we finalized an expanded model start date of January 1, 2018.

In this proposed rule, we propose a new start date for the furnishing of MDPP services within the expanded model of April 1, 2018. That is, MDPP suppliers will not be able to furnish MDPP services, or to receive payment for these services, prior to April 1, 2018. We note that if finalized as part of the CY 2018 PFS, the supplier enrollment and compliance policies will
become effective on January 1, 2018. This change to delay the furnishing of MDPP services would allow time for organizations to enroll in Medicare before they begin furnishing and billing for MDPP services.

In the CY 2017 PFS final rule (81 FR 80459), we described a possible payment structure for MDPP services, but deferred full development of the payment structure to future rulemaking. In section III.K.2.d. of this proposed rule, we discuss our proposed payment structure for MDPP services. This proposal takes into consideration the significant number of public comments we received in response to the possible payment structure we described in the July 15, 2016 MDPP proposed rule. We also are proposing payment policies for instances in which an MDPP beneficiary switches MDPP suppliers.

In the CY 2017 PFS final rule (81 FR 80471 through 80474), we required CDC-recognized organizations that will bill Medicare for MDPP services to enroll in Medicare as MDPP suppliers. We also finalized the requirements for coaches furnishing MDPP services. We finalized policies regarding CDC Diabetes Prevention Recognition Program (DPRP) full recognition for MDPP suppliers and we indicated an intention to propose policies in future rulemaking regarding whether a DPP organization without full CDC recognition could enroll as an MDPP supplier. We are proposing an interim MDPP preliminary recognition standard in section III.K.2.e. of this proposed rule. Also, in this section of this proposed rule, we are proposing revisions to the supplier eligibility and enrollment requirements, including establishment of standards and implementation of appropriate program integrity safeguards. In section III.K.2.f. of this proposed rule, we are proposing policies related to MDPP beneficiary engagement incentives furnished by MDPP suppliers.
In the CY 2017 PFS final rule (81 FR 80459), we deferred establishing policies related to organizations delivering “virtual” DPP services, where services are not furnished in person. In section III.K.3. of this proposed rule, we explain that the MDPP expanded model covers in-person MDPP services (other than ad hoc virtual make-up sessions discussed in section III.K.2.c.iv.(3) of this proposed rule), and thus, explain why we are not currently making any proposals related to MDPP services furnished 100 percent virtual and state that we are considering a separate model under CMS’s Innovation Center authority to test and evaluate virtual DPP services.

2. Proposed Policy Changes

a. Proposed Changes to Effective Date of MDPP Services

In the CY 2017 PFS final rule, we established at §410.79(a) that MDPP services would be available on January 1, 2018. We are proposing to change §410.79(a) to state that MDPP services would be available on April 1, 2018. We are proposing this change because we want to ensure that MDPP suppliers have sufficient time to enroll in Medicare after the effective date of the CY 2018 PFS final rule.

Therefore, beneficiaries will not be able to receive MDPP services immediately on January 1, 2018 due to the time needed for supplier enrollment. For this reason, we are proposing April 1, 2018 as the expanded model start date, which we believe allows a sufficient amount of time (90 days) for eligible suppliers to enroll in Medicare before furnishing and billing for MDPP services. Subject to this proposed change, the following regulatory provisions, if finalized, would be effective April 1, 2018: §414.84 related to payment for MDPP services; and §424.210 related to beneficiary engagement incentives. All other sections, if finalized, will be effective on January 1, 2018, including the policies proposed in section III.K.2.e. related to
supplier enrollment and compliance. We seek comment on this new expanded model start date and whether 90 days is a sufficient amount of time for organizations to enroll in Medicare and prepare to furnish and bill for MDPP services.

b. Proposed Changes to the Set of MDPP Services

In the CY 2017 PFS final rule, we established the parameters of MDPP services. The policies and terms proposed in this proposed rule seek to clarify, build on, and at times change these previously finalized policies. In particular, we propose to refine and add terms related to the different aspects of “MDPP services.” In this proposed rule, we propose to slightly refine the term “MDPP services” to refer to structured health behavior change sessions that are furnished under the MDPP expanded model with the goal of preventing diabetes among Medicare beneficiaries with prediabetes, and that follow a CDC-approved curriculum (proposed §410.79(b)). The sessions provide practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to maintaining weight loss and a healthy lifestyle.

In the preamble to the CY 2017 PFS final rule, we referenced the set of MDPP services covered under the expanded model as the “MDPP benefit.” In this proposed rule, we propose to update this terminology. In cases where we would have previously referred to the term “benefit” to describe the entire set of MDPP sessions covered under the MDPP model, we propose to use the phrase “set of MDPP services.” “Set of MDPP services” means the series of MDPP sessions, composed of core sessions, core maintenance sessions, and ongoing maintenance sessions, offered over the course of the MDPP services period (proposed §410.79(b)).

In cases where we would have previously used the term “benefit” to describe a period of time, we propose to refer to the “MDPP services period.” The MDPP services period means the
time period, beginning on the date an MDPP beneficiary attends his or her first core session, over which the set of MDPP services is furnished to the MDPP beneficiary, to include the core services period described in paragraph §410.79(c)(2)(i) and, subject to paragraph §410.79(c)(3), one or more ongoing maintenance session intervals during the ongoing services period described in paragraph §410.79(c)(2)(ii) (proposed §410.79(b)). The duration of the MDPP services period is discussed further in section III.K.2.c.iv. of this proposed rule. As noted throughout this section, the term “benefit” would no longer be used. We propose to remove the term “MDPP core benefit” from the list of definitions.

In the CY 2017 PFS final rule, we included a definition for “core sessions” that referred to the set of core sessions covered under the MDPP expanded model. We propose to revise the definition for “core sessions,” and instead define the singular “core session” as an MDPP service that is furnished by an MDPP supplier to an MDPP beneficiary during months 1 through 6 of the MDPP services period, is approximately 1 hour in length, and adheres to a CDC-approved DPP curriculum for core sessions (proposed §410.79(b)). We believe that having a definition for the individual core session would be more uniform with other MDPP definitions, which are defined in the singular form. We propose to revise the definition of “core maintenance session” as an MDPP service that is furnished by an MDPP supplier to an MDPP beneficiary during a core maintenance session interval, is approximately 1 hour in length, and adheres to a CDC-approved DPP curriculum for maintenance sessions (under proposed revised §410.79(b)).

We propose to revise the definition of an “ongoing maintenance session” as an MDPP service that is furnished by an MDPP supplier to an MDPP beneficiary during an ongoing maintenance session interval, is approximately 1 hour in length and adheres to a CDC-approved DPP curriculum for maintenance sessions (proposed revised §410.79(b)). The proposed time
period over which MDPP suppliers offer ongoing maintenance sessions, which differs from our previously finalized policy, is discussed in section III.K.2.b.i. of this proposed rule.

We propose to add a definition for “MDPP session,” which means a core session, a core maintenance session, or an ongoing maintenance session (proposed §410.79(b)).

We invite public comments on these proposals.

i. Ongoing Maintenance Session Time Limit

In the CY 2017 PFS final rule, we finalized that “MDPP eligible beneficiaries,” a term we now propose to remove and replace with “MDPP beneficiary,” as described further in section III.K.2.c. of this proposed rule, would have Medicare coverage for ongoing maintenance sessions for an unspecified length of time, provided that they maintained the required minimum weight loss, which is 5 percent weight loss from baseline. Based on public comments indicating the limited administrative and operational capability of many MDPP suppliers to provide ongoing maintenance sessions for an individual indefinitely (81 FR 80468), we stated our intent to propose a limit on the number or duration of ongoing maintenance sessions to be covered in the set of MDPP services, although we did not finalize a policy that would do so.

In this rule, we propose a 2-year limit on Medicare coverage for ongoing maintenance sessions (proposed §410.79(c)(2)(ii)). The CMS Chief Actuary noted in the certification of the expansion of the DPP model test that continued participation in a type 2 diabetes DPP after 3 years has generally been untested. In addition, a DPP clinical trial conducted by the National Institutes of Health from 1996 to 2001 followed participants in a DPP for 3 years and found that, at the end of the study, diabetes incidence was reduced by 58 percent in the group that received a DPP lifestyle intervention when compared to the placebo group.\(^7\) Based on the lack of evidence

about DPP services beyond 3 years and evidence of positive effects from DPP participation for 3 years, in this proposed rule, we propose a total MDPP services period of up to 3 years (consisting of 1 year of core sessions and core maintenance sessions, followed by up to 2 years of ongoing maintenance sessions, (proposed §410.79(b)).

We considered alternatives to this proposal, such as limiting Medicare coverage for ongoing maintenance sessions to 1 year, which would limit the total MDPP services period to 2 years. Because the CDC DPRP does not require organizations to offer ongoing maintenance sessions, we also considered not covering ongoing maintenance sessions altogether, which would limit the total MDPP services period to 1 year. However, we believe that beneficiaries can benefit from maintenance sessions beyond the 6 months of core maintenance sessions because weight loss is difficult to achieve and can be even more difficult to sustain. We believe that the behavior changes necessary to sustain weight loss will be more deeply ingrained through beneficiary participation in ongoing maintenance sessions. Existing evidence also supports the effectiveness of participation in a DPP through 3 years.

We did not consider alternatives that would extend Medicare coverage for ongoing maintenance sessions beyond 2 years, and therefore, create an MDPP services period that would last longer than 3 years. Therefore, we propose to continue to include ongoing maintenance sessions, but with a limit of up to 2 years. As stated earlier, we believe there is not enough evidence available to support the effectiveness of participation in a DPP beyond 3 years. We also believe, based on public comments received in response to the July 15, 2016 MDPP proposed rule, that many suppliers have limited administrative and operational capacity to offer MDPP ongoing maintenance sessions indefinitely to all MDPP beneficiaries who maintain eligibility. As noted in section III.K.2.e.iv.4 of this proposed rule, an example of a capacity limit
could include a situation where an MDPP supplier has met its class size maximum and therefore could not accept additional beneficiaries. We are inviting public comments on our proposal and the alternatives we considered.

ii. MDPP Services Period Clarifications

At §410.79(b), we propose to remove the existing definition of “maintenance session bundle,” and to establish new definitions for “core maintenance session interval,” and “ongoing maintenance session interval,” which we believe will more directly reflect the structure of the set of MDPP services, as well as support the proposed policies in this proposed rule. Through these proposed definition changes, we are seeking to clarify the differences between the two types of intervals. We propose to define “core maintenance session interval” as one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers an MDPP beneficiary at least one core maintenance session per month. We propose to define “ongoing maintenance session interval” as one of the up to eight consecutive 3-month time periods during the ongoing services period described in paragraph §410.79(c)(2)(ii), during which an MDPP supplier offers at least one ongoing maintenance session to an MDPP beneficiary per month.

We are making the proposal to use the term “interval” instead of “bundle” because the proposed performance payments are tied to attendance and weight loss performance goals and, in aggregate, constitute the payment to MDPP suppliers for furnishing MDPP services during the MDPP services period, but they do not provide specific payments for a particular subset of sessions. Therefore, we believe that the term “bundle” is not appropriate for describing performance payments for these time intervals. The proposed new terms allow us to more appropriately describe the relationship of the performance payments to the specific time periods.
where performance is measured. Furthermore, we propose to define “make-up session” as a core session, a core maintenance session, or an ongoing maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session, core maintenance session, or ongoing maintenance session (proposed at §410.79(b)). We propose to define “virtual make-up session” as a make-up session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for virtual sessions (proposed §410.79(b)). Policies describing the parameters of make-up sessions and virtual make-up sessions are described further in section III.K.2.c.iv.(3).

We propose an additional term that helps describe key aspects of the MDPP expanded model: “performance goal.” This term refers to an attendance or weight loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment (proposed §414.84(a)). Because we propose this term that more broadly speaks to the performance goals of this expanded model, we propose to remove the definition of “maintenance of weight loss.” We also propose to move the definition of “coach” from §410.79(b) to §424.205(a) (we propose in section III.K.2.e to redesignate §424.59, Requirements for Medicare Diabetes Prevention Program suppliers to §424.205). We propose to revise the definition of “MDPP supplier” to mean an entity that is enrolled in Medicare to furnish MDPP services as provided in §424.59 (proposed to be redesignated as §424.205).

We invite public comments on these proposals.

c. Proposed Changes Related to Beneficiary Eligibility

In the CY 2017 PFS final rule, we established the eligibility criteria for Medicare beneficiaries to have coverage of the set of MDPP services, codified at §§410.79(c)(1) and 410.79(d), respectively. We previously finalized that an individual who met these criteria would
be referred as an “MDPP eligible beneficiary.” However, in this proposed rule, we propose to remove this term, and instead, add the definition of “MDPP beneficiary” to mean a Medicare beneficiary who meets the criteria specified in paragraph §410.79(c)(1)(i), who has initiated the MDPP services period by attending the first core session, and for whom the MDPP services period has not ended as specified in paragraph §410.79(c)(3) (proposed §410.79(b)). We believe that this revised definition will provide more clarity about when a beneficiary qualifies to receive MDPP services. We propose to remove the definition of “MDPP eligible beneficiary” to avoid confusion between the two definitions, and we propose conforming changes to §410.79 to remove the term “MDPP eligible beneficiary” and use the term “MDPP beneficiary” in its place, where appropriate.

In the CY 2017 PFS final rule (81 FR 80470), we specified at §410.79(c)(1) that Medicare beneficiaries are eligible for MDPP services if they meet all of the following criteria:

- Are enrolled in Medicare Part B.
- Have, as of the date of attendance at the first core session, a body mass index (BMI) of at least 25 if not self-identified as Asian or a BMI of at least 23 if self-identified as Asian (please see our discussion of BMI parameters in the CY 2017 PFS final rule at 81 FR 80468).
- Have, within the 12 months prior to attending the first core session, a hemoglobin A1c test with a value between 5.7 and 6.4 percent, a fasting plasma glucose of 110-125 mg/dL, or a 2-hour plasma glucose of 140-199 mg/dL (oral glucose tolerance test).
- Have no previous diagnosis of type 1 or type 2 diabetes (other than gestational diabetes).
- Do not have end-stage renal disease (ESRD).
In this proposed rule, we propose changes to these eligibility criteria at §410.79(c)(1) to clarify the eligibility limitations related to previous type 1 or type 2 diabetes diagnosis (described further in section III.K.2.c.ii. of this proposed rule), move and edit the regulation text that specifies that each beneficiary can only receive the set of MDPP services once in their lifetime (described further in section III.K.2.c.iii. of this proposed rule), and make editorial changes so that the provisions are specific to an individual beneficiary. We also are taking this opportunity to clarify some of these eligibility criteria.

i. Clarifying MDPP Eligibility Criteria Related to Gestational Diabetes and End-Stage Renal Disease (ESRD)

We note that we are not excluding beneficiaries with a prior history of gestational diabetes from eligibility for MDPP services, while beneficiaries with a prior history of a diagnosis of type 1 or type 2 diabetes are ineligible. The eligibility criteria are intended to identify a beneficiary at high risk for the development of type 2 diabetes in an individual that has not been diagnosed with type 1 or type 2 diabetes. Gestational diabetes is a condition that develops during pregnancy and typically resolves after delivery, although an individual with a history of gestational diabetes is at increased risk of subsequent type 2 diabetes development and may benefit from the set of MDPP services. Because of the clinical differences between gestational diabetes and type 1 or type 2 diabetes, we determined that it was appropriate not to exclude a beneficiary with a prior history of gestational diabetes from eligibility for MDPP services.

We also are clarifying that a beneficiary who is diagnosed with ESRD after having begun receiving MDPP services would lose eligibility. We do not believe MDPP services are appropriate for beneficiaries with ESRD because beneficiaries with ESRD require dialysis, and
the nutrition requirements for individuals on dialysis are very specific and therefore MDPP curriculum will not apply. We believe that a beneficiary receiving MDPP services who develops ESRD will be best suited by ceasing to receive MDPP services and receiving attention by other health care professionals specifically suited to address his or her condition. Additionally, individuals with ESRD were not included in the DPP model test. Suppliers can use the online HIPAA Eligibility Transaction System (HETS) to verify if a beneficiary has ESRD by checking his or her eligibility status as a Part B or ESRD Medicare beneficiary. Suppliers can find more information on this system at https://www.cms.gov/hetshelp/. We recognize that some Medicare beneficiaries may have other serious conditions, such as heart disease or cancer, and therefore may also have specific dietary requirements. We recommend that beneficiaries with complex dietary needs consult their health care provider as to whether they should participate in MDPP.

In summary, a beneficiary must maintain Medicare Part B coverage and not have ESRD throughout the duration of the MDPP services period to remain eligible to receive coverage for MDPP services. In conjunction with our proposal in this proposed rule related to diabetes diagnosis (explained further in section III.K.2.c.ii. of this proposed rule), a beneficiary must meet the eligibility requirements related to prediabetes and diabetes (including BMI, blood test results, and no diagnosis of diabetes other than gestational diabetes) as of the date of attendance at the first core session.

We invite public comments on these proposals.

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ii. Diabetes Diagnosis during the MDPP Services Period

In the CY 2017 PFS final rule, we finalized that to be eligible for coverage for the set of MDPP services, a Medicare beneficiary must have prediabetes, as shown through a qualifying BMI and blood test results, and must have no previous diagnosis of type 1 or type 2 diabetes (other than gestational diabetes). We received public comments in response to the July 15, 2016 MDPP proposed rule that asked whether a beneficiary would remain eligible for the set of MDPP services if the beneficiary developed diabetes during the MDPP services period. In the CY 2017 PFS final rule, we deferred action in response to these public comments and are now addressing them in this proposed rule.

We propose that the diabetes diagnosis exclusion applies only at the time of the first core session (that is, if a beneficiary develops diabetes during the MDPP services period, it would not affect the beneficiary’s eligibility to continue receiving MDPP services). Specifically, we propose to revise the eligibility requirements for MDPP services to state that a beneficiary has, as of the date of attendance at the first core session, no previous diagnosis of diabetes, other than gestational diabetes (proposed §410.79(c)(1)(i)(E)). This proposed policy is based in part on the fact that the DPP model test, which demonstrated cost savings, did not exclude from the model individuals who developed diabetes. Additionally, whereas suppliers can check HETS to verify a beneficiary’s ESRD status fairly easily, we believe requiring a supplier to reassess other beneficiary eligibility criteria such as diabetes status and blood test results, and subsequently removing those who no longer meet the eligibility criteria is impractical and unduly burdensome.

Alternatively, we considered deeming any beneficiary who develops diabetes during the MDPP services period to be ineligible to continue to receive coverage for MDPP services because these services are intended to be preventive. If a beneficiary progresses to type 2
diabetes, other treatment options, such as Diabetes Self-Management Training (DSMT), may be more appropriate than services that seek to prevent a condition the beneficiary already has. However, it is important to note that the receipt of MDPP services does not preclude a beneficiary from accessing other treatments for diabetes during the time period that the beneficiary is covered for MDPP services. An MDPP beneficiary who ultimately also receives DSMT at some time during the MDPP services period because he or she develops diabetes after beginning the set of MDPP services will receive different types of information and training. For example, a beneficiary receiving DSMT furnished by certified diabetes educators acquires knowledge for self-care and lifestyle changes including blood sugar monitoring, insulin usage, medication management, and crisis management. In contrast, MDPP services are furnished by trained coaches who teach patients with prediabetes how to lower their risk of progressing to type 2 diabetes with methods that do not include medication or other interventions for patients diagnosed with diabetes. Despite some common elements, the interventions for the MDPP expanded model and the DSMT benefit target different populations and furnish different services.

We are seeking public comments on our proposal and whether individuals who develop diabetes during the MDPP services period should continue to be eligible for coverage of MDPP services for the full duration of the MDPP services period.

iii. Once-Per-Lifetime Set of Services

In the CY 2017 PFS final rule, we specified that coverage for the set of core MDPP services is available only once per lifetime for each MDPP beneficiary (codified at §410.79(d)(1)). In this rule, we propose to delete §410.79(d)(1) and move this provision to proposed §410.79(c)(1)(i)(B) to place it with other MDPP beneficiary eligibility criteria. We
also propose to edit this provision to specify that coverage for the full set of MDPP services, inclusive of ongoing maintenance sessions as opposed to only core MDPP services, is available only once per lifetime per MDPP beneficiary. Now that we propose to limit the ongoing services period to 2 years, we believe that this proposed revision is necessary to clarify that coverage for the entire set of MDPP services is subject to this limitation—otherwise, the once-per-lifetime limitation has no practical effect because an MDPP beneficiary could continue to attend ongoing maintenance sessions long after the MDPP beneficiary has completed the core services period. In addition, for the reasons stated previously, we do not have evidence to support coverage of MDPP services for more than 3 years. We also are clarifying that the once-per-lifetime coverage limit applies to a beneficiary who receives a set of MDPP services under the MDPP model expansion. This limitation would not apply to beneficiaries who participated in a DPP as part of the DPP model test unless they receive the set of MDPP services under the MDPP expanded model. We invite public comments on our proposal.

In the CY 2017 PFS final rule, we stated that beneficiaries could self-report to MDPP suppliers that they had not previously received MDPP services. We recognize that self-reported information may not be the most reliable source for MDPP suppliers to use before submitting claims for MDPP beneficiaries, and there is a risk that information that is inaccurately self-reported could result in the denial of payments for MDPP services. We are considering ways MDPP suppliers would be able to reliably verify if a beneficiary has received coverage of MDPP services from another supplier, such as through a standardized tracker described in section III.K.2.d.v of this proposed rule, and we are seeking public comments on any additional ways MDPP suppliers could access this information. We intend to provide administrative guidance on
any resources to assist MDPP suppliers in identifying beneficiaries’ previous receipt of covered MDPP sessions, as appropriate.

iv. Eligibility throughout the MDPP Services Period

In the CY 2017 PFS final rule, we specified the minimum number and frequency of sessions that MDPP suppliers must offer to MDPP beneficiaries (codified at §§410.79(c)(2)(i) and 410.79(c)(2)(ii)). We finalized that MDPP suppliers must furnish ongoing maintenance session intervals to MDPP eligible beneficiaries who have maintained 5 percent weight loss from their baseline weight as measured during the previous maintenance session interval. As defined at §410.79(b), “baseline weight” is the MDPP beneficiary’s body weight recorded during that beneficiary’s first core session.

However, because in this proposed rule we propose to tie payment for MDPP services to the beneficiary’s achievement of performance goals, we propose additional changes to tie the beneficiary’s eligibility for continued coverage of ongoing maintenance session intervals to his or her achievement of performance goals, namely requiring a minimum level of attendance. Because our proposed policies for payment and coverage differ somewhat, we are addressing them separately below.

(1) MDPP Services Period

As discussed in section III.K.2.b. of this proposed rule, we propose to revise §410.79(c)(2), which describes MDPP services periods, to specify that the MDPP services period means the time period, beginning on the date an MDPP beneficiary attends his or her first core session, over which the set of MDPP services is furnished to the MDPP beneficiary, to include the core services period described in paragraph §410.79(c)(2)(i) and, subject to paragraph
§410.79(c)(3), one or more ongoing maintenance session intervals during the ongoing services period described in paragraph §410.79(c)(2)(ii).

We propose to revise §410.79(c)(2) to specify that there are two service periods in which Medicare will cover MDPP services for a beneficiary: the core services period; and the ongoing services period. Together these would make up the MDPP services period. The core services period is the first 12 months of the MDPP services period, and consists of core sessions and core maintenance sessions. There are 16 core sessions that are offered at least a week apart in months 1 through 6, beginning on the date of attendance at the first core session. Core maintenance sessions are offered at least once per month in months 7 through 12 of the core services period. We propose to move the requirements for MDPP suppliers to offer these services to §424.205(d)(9) because they are more appropriately included among other requirements for MDPP suppliers. Consistent with our policies finalized in the CY 2017 PFS final rule, we do not condition coverage for the core services period upon weight loss or attendance. Medicare will pay for the set of core MDPP services, regardless of how many sessions the beneficiary attends and regardless of his or her weight loss. However, we note that an MDPP beneficiary must attend at least one core session to initiate the MDPP services period.

These proposals would align with CDC’s 1-year curriculum, divided into two 6-month periods. We recognize that framing the MDPP services period in terms of months may cause some confusion because the CDC terminology uses weeks. However, we believe that framing the MDPP services period in months would better align with our proposed payment structure. We did not make eligibility for the core maintenance sessions contingent upon an attendance-based performance goal; because the CDC DPP curriculum covers 12 months of sessions, we believe that coverage for the 12 months of the core services period should be available to all
MDPP beneficiaries, regardless of attendance. The 12-month CDC DPP curriculum is based on evidence from the original DPP randomized clinical trial, and the curriculum used in that trial, which achieved a 58 percent reduction in type 2 diabetes risk (with 71 percent reduction in those over age 60).  

As discussed in section III.K.2.e.iv.4 of this proposed rule, MDPP suppliers must offer a minimum of 16 core sessions, no more frequently than once each week, in months 1 through 6, and at least 1 core maintenance session each month in months 7 through 12 of the core services period. However, some MDPP suppliers may choose to furnish more than the minimum number of sessions, and these proposed coverage parameters would allow beneficiaries to receive more than the minimum number of sessions if the MDPP supplier elects to furnish them.

We invite public comments on our proposals.

(2) Ongoing Services Period

As discussed in section III.K.2.b.i. of this proposed rule, we propose to revise §410.79(c)(2)(ii) to clarify that the ongoing services period consists of up to eight 3-month ongoing maintenance session intervals offered during months 13 through 36 of the MDPP services period. Medicare’s coverage of the ongoing services period is subject to limitations proposed subsequently in this section.

(a) Eligibility for the Ongoing Services Period

Our existing regulations at §410.79(b) affirm that Medicare will cover MDPP services in the first 12 months of the MDPP services period, without regards to a beneficiary’s achievement of performance goals, whereas §410.79(d)(2) specifies that, for coverage of ongoing

maintenance sessions, the beneficiary must have achieved weight loss of 5 percent from his or her baseline weight. In this proposed rule, we propose to delete §410.79(d)(2) and move this provision to §410.79(c)(1) with other MDPP beneficiary eligibility criteria. We also propose to add paragraph (c)(1)(ii) to §410.79 to specify that beneficiaries must also attend at least one in-person core maintenance session in months 10 through 12 of the MDPP services period and achieve or maintain required minimum weight loss at a minimum of one in-person session during the final core maintenance session interval to be eligible for coverage of the first ongoing maintenance session interval. We propose to establish that a beneficiary must attend at least one in-person core maintenance session in months 10 through 12 of the MDPP services period because, as stated in the CY 2017 PFS final rule, an MDPP beneficiary must achieve at least 5 percent weight loss from baseline at least once during the previous maintenance session interval to have coverage of an ongoing maintenance session.

Because we propose that weight measurements used for determining beneficiary eligibility for coverage or supplier payment must be taken in person by an MDPP supplier at an MDPP core maintenance or ongoing maintenance session (proposed §410.79(c)(1)(iv)), a beneficiary must attend at least one in-person core maintenance session during months 10 through 12 to have his or her weight measured to determine whether he or she qualifies for coverage of the first ongoing maintenance session interval. We believe that in-person measurements are the most feasible method for weight ascertainment at this time for services where the beneficiary would have regular in-person sessions with the MDPP supplier. We believe that self-reported weight loss is not reliable for the purposes of determining continued coverage of MDPP services for a beneficiary. We invite public comments on these proposals.

(b) Eligibility for Ongoing Maintenance Session Intervals 2 through 8
In addition to achieving weight loss performance goals, as previously finalized in the CY 2017 PFS final rule, we propose that beneficiaries must also meet an attendance-related performance goal in order for Medicare to cover ongoing maintenance session intervals. We propose to add paragraph (c)(1)(iii) to §410.79 to specify that for coverage of ongoing maintenance session intervals 2 through 8, an MDPP beneficiary must attend at least 3 ongoing maintenance sessions during the previous ongoing maintenance session interval, in addition to maintaining 5 percent weight loss from baseline at least once during the previous ongoing maintenance session interval.

We believe that adding an attendance-related performance goal during the ongoing services period is important because it will provide an incentive to keep MDPP beneficiaries engaged after the core services period. MDPP beneficiaries who meet the specified attendance and weight loss goals will have Medicare coverage of ongoing maintenance sessions, which are a part of the set of MDPP services, but not a part of the CDC DPP curriculum. We believe that the subsequent attendance goal requirements during ongoing maintenance session intervals will motivate beneficiaries to take on more individual responsibility for their behavior changes over time because coverage of these services is dependent upon their attendance and achievement and maintenance of weight loss.

In addition, this proposed policy closely aligns with our proposed policy for supplier payment for ongoing maintenance session intervals. As described further in section III.K.2.d.iii.5. of this proposed rule, we propose that a supplier would be paid for furnishing an ongoing maintenance session interval only if the MDPP beneficiary both attended three sessions, as well as maintained a 5 percent weight loss from baseline measured at least once in that interval. However, in light of our proposal to pay MDPP suppliers upon the beneficiary’s
attendance of three ongoing maintenance sessions (in addition to maintaining at least a 5 percent weight loss), we believe that we similarly need to have attendance goals for beneficiaries to continue to have coverage of ongoing maintenance sessions. Without requiring attendance, an MDPP beneficiary who maintained 5 percent weight loss but only attended two ongoing maintenance sessions in an ongoing maintenance session interval would be eligible for coverage of ongoing maintenance sessions, but the supplier would not receive payment for furnishing that ongoing maintenance session interval. In effect, the MDPP supplier could be required to furnish up to 24 months of MDPP services without payment. For this reason, we propose to require beneficiaries to attend all three sessions within an ongoing maintenance session interval to have coverage of the subsequent interval.

We considered an alternative where a beneficiary would have continued coverage of ongoing maintenance session intervals if he or she attends at least one in-person ongoing maintenance session during an ongoing maintenance session interval, as long as that beneficiary maintained at least 5 percent weight loss from baseline at least once during that interval. However, we do not believe that this alternative would align with our proposed supplier payment requirements for ongoing maintenance sessions discussed in section III.K.2.d.iii.5 of this proposed rule, which would require suppliers to furnish, and the beneficiary to attend, all three sessions of the ongoing maintenance session interval for the supplier to receive payment for that interval. We are inviting public comments on our proposal and the alternative we considered.

(c) Limitations on the Set of MDPP Services

In this proposed rule, we propose to add §410.79(c)(3) to specify that coverage of the MDPP services period would end upon completion of the core services period for a beneficiary that is not eligible for the first ongoing maintenance session interval as proposed under
§410.79(c)(1)(ii); that is, if the beneficiary does not attend at least one in-person core maintenance session during the second core maintenance session interval and/or does not achieve the required minimum weight loss during this interval. For any beneficiary who is eligible for at least one ongoing maintenance sessions interval, but who does not meet the requirements for coverage of a subsequent interval based on failure to meet attendance or weight loss goals proposed at §410.79(c)(1)(iii), the beneficiary’s coverage of the set of MDPP services would end upon completion of his or her current ongoing maintenance session interval. It is important to note that proposed performance payments, discussed in section III.K.2.d.iii.5. of this proposed rule, would be tied to the achievement of the same performance goals a beneficiary must meet to have coverage for the ongoing maintenance session intervals. Therefore, if an MDPP beneficiary does not meet weight loss or attendance goals to access the subsequent ongoing maintenance session interval, the supplier will not receive payment for that ongoing maintenance session interval or any subsequent performance payments related to that beneficiary.

We are inviting public comments on these proposed policies.

(d) Beneficiaries Who Change MDPP Suppliers during the MDPP Services Period

In the CY 2017 PFS final rule, we indicated that a beneficiary may change MDPP suppliers at any time. However, we deferred to future rulemaking specific policies to address coverage of and payment for MDPP services when beneficiaries change MDPP suppliers. In this proposed rule, we are clarifying that a beneficiary may change MDPP suppliers at any time during his or her MDPP services period, subject to beneficiary eligibility requirements. Based on evidence from the CDC DPRP, we believe that the instances of beneficiaries changing MDPP suppliers will be relatively infrequent. However, we intend to monitor how often beneficiaries change MDPP suppliers, as well as MDPP suppliers’ billing patterns to detect any aberrant
billing patterns suggestive of fraudulent or discriminatory practices. Payment policies related to when a beneficiary changes MDPP suppliers are discussed in section III.K.2.d.v.

(3) Make-Up Sessions

(a) General Requirements.

In this proposed rule, we propose at §410.79(d)(1) that suppliers may offer make-up sessions to an MDPP beneficiary who missed a regularly scheduled session. As defined at proposed §410.79(b), “make-up session” means a core session, core maintenance session, or ongoing maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session, core maintenance session, or ongoing maintenance session. Make-up sessions may be delivered in person or virtually, although virtual make-up sessions are subject to additional requirements proposed in this rule (and the term “virtual make-up session” is separately defined). We propose the availability of make-up sessions to be consistent with CDC’s DPRP standards and to ensure that MDPP beneficiaries have the opportunity to receive the full DPRP curriculum, even if they are unable to attend a particular regularly scheduled MDPP session.

We propose that the curriculum delivered during a make-up session must address the same CDC-approved DPP curriculum topic as the session that the beneficiary missed (proposed §410.79(d)(1)(i)). To be consistent with CDC’s proposed 2018 DPRP standards, we propose that the MDPP supplier may furnish to the beneficiary a maximum of one make-up session on the same day as a regularly scheduled session (proposed §410.79(d)(1)(ii)) and the MDPP supplier may furnish to the beneficiary a maximum of one make-up session per week (proposed §410.79(d)(1)(iii)).

(b) Virtual Make-Up Sessions
There is a growing area of research examining the effectiveness of DPP delivered virtually. CDC began recognizing Virtual DPP organizations in 2015 and emerging evidence suggests that virtual delivery of DPP services can show similarly successful participant weight loss and health benefits to DPP delivered in other settings, including among Medicare-age participants. Since CDC’s DPRP standards permit virtual make-up sessions, and we recognize that MDPP beneficiaries may encounter situations where they are unable to attend in-person make-up sessions, we propose to allow MDPP suppliers to offer a limited number of virtual make-up sessions (proposed §410.79(d)(2)). As proposed in §410.79(b), “virtual make-up session” means a make-up session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for virtual sessions. All requirements proposed in §410.79(d)(1) apply to virtual make-up sessions. In addition, we propose that virtual make-up sessions are subject to additional requirements.

First, as indicated by the applicable definition, virtual make-up sessions must be furnished in a manner consistent with CDC’s DPRP standards for virtual sessions (proposed §410.79(d)(2)(i)). To align with CDC’s DPRP standards, virtual make-up sessions refer to any modality, or method of furnishing MDPP services, that is not in person. This includes, but is not limited to:

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(1) Furnishing services online where the behavior change program is furnished 100 percent online, with participants accessing course resources and a coach via a computer, laptop, tablet, smart phone, or other device with Internet access. This modality requires that the MDPP beneficiary have an Internet connection to participate in all aspects of the virtual make-up session;

(2) Furnishing services online with other means of support by a coach (for example, telecommunications, video conferencing). This modality requires that the MDPP beneficiary have an Internet connection for some aspects of the virtual make-up session, but not all; and

(3) Distance learning, where a coach is present in one location and participants are calling, video-conferencing, or otherwise using telecommunications technology to access the coach from another location. This modality does not require that the MDPP beneficiary have an Internet connection for any of the aspects of the virtual make-up session.

By defining MDPP virtual make-up sessions as being consistent with CDC’s DPRP standards for virtual sessions, we allow our definition to change over time as such standards are updated.

Second, a supplier may only offer virtual make-up sessions based on an individual MDPP beneficiary’s request (proposed §410.79(d)(2)(ii)). A supplier may not cancel a regularly scheduled MDPP session and offer the session to all MDPP beneficiaries virtually. However, the supplier may cancel a regularly scheduled MDPP session and offer the session to all MDPP beneficiaries in person. We believe that this is necessary to ensure that the MDPP expanded model remains a model predominantly delivered in person. Individual beneficiary needs may be accommodated, but suppliers should not use virtual make-up sessions as a means to move toward virtually-delivered MDPP sessions more generally.
Third, to further ensure that MDPP services are largely provided in-person, we propose at §410.79(d)(2)(iii) that a supplier may offer: (a) no more than 4 virtual make-up sessions within the core services period to an MDPP beneficiary, of which no more than 2 virtual make-up sessions may be core maintenance sessions; and (b) no more than 3 virtual make-up sessions that are ongoing maintenance sessions to an MDPP beneficiary during any rolling 12-month time period. At §410.79(d)(3), we propose that these same limitations on the number of virtual make-up sessions also apply for the purposes of determining whether a beneficiary has attended a sufficient number of MDPP sessions in order to be eligible for ongoing maintenance sessions (proposed §410.79(c)(1)) and for assessing whether a beneficiary has met the attendance-related performance goals used to determine whether an MDPP supplier is eligible to receive a performance payment (proposed §414.84(b)). The limitation on the number of make-up sessions is not applicable to in-person make-up sessions.

We assume not all suppliers will have the ability to offer virtual make-up sessions, and we are not requiring suppliers to offer virtual make-up sessions. Conversely, an MDPP supplier could offer only virtual make-up sessions and no in-person make-up sessions if the supplier chooses as long as the proposed limits for these sessions are not exceeded. We believe that allowing fewer than these proposed number of virtual make-up sessions will make it difficult for suppliers to meet DPRP standards, and therefore remain enrolled as an eligible MDPP supplier. However, the DPP model test only offered in-person sessions (no virtual sessions) and therefore the MDPP expanded model is intended to predominantly offer services in person. Allowing more than the proposed number of virtual make-up sessions would not support an evaluation of an in-person MDPP curriculum. We seek comment on our proposals and specifically on the proposed limitations on virtual make-up sessions.
We considered the following alternatives to this proposal. We considered not allowing any make-up sessions to be furnished virtually. However, we believe that this would place undue restrictions on MDPP suppliers who are willing and would like to offer virtual make-up sessions to MDPP beneficiaries, particularly if these are offered to other DPP participants who are not Medicare beneficiaries.

We also considered allowing an MDPP supplier to furnish between one and three sessions within the core services period and either one or two ongoing maintenance sessions each year as virtual make-up sessions per MDPP beneficiary. However, we believe that allowing fewer sessions to be furnished as virtual make-up sessions than proposed would not provide sufficient flexibility for MDPP suppliers to meet CDC’s DPRP standards, which require organizations to meet attendance requirements for their panel of participants. Organizations may struggle to meet DPRP attendance requirements without the flexibility to provide virtual make-up sessions.

We also considered permitting suppliers to offer any number of virtual make-up sessions, and for attendance at any number of virtual make-up sessions to count toward attendance goals. However, as stated previously, since the DPP model test only offered DPP services in person, the MDPP expanded model is intended to predominantly offer MDPP sessions in person as well. Therefore we believe that it is important to limit the number of virtual make-up sessions so that MDPP beneficiaries are predominantly receiving MDPP sessions in person.

We propose that the payment policies detailed in section III.K.2.d. of this proposed rule apply to virtual make-up sessions. Specifically, as indicated in sections III.K.2.c.1.iv. and III.K.2.d.iii.10.b. of this proposed rule, weight measurements used for the purposes of determining the achievement or maintenance of weight loss for weight loss performance
payments, or for determining eligibility for coverage of ongoing maintenance sessions, would be required to be taken at an in-person session, not during a virtual make-up session. We are seeking public comments on these proposals and the alternatives considered.

d. Payment for MDPP Services

i. MDPP Payment Discussion in Prior Rulemaking

In the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416), we discussed a potential MDPP payment structure and the associated payment amounts and sought information from the public to inform future MDPP proposals. We received a number of public comments on these topics and have considered this information in the development of our proposals for the MDPP payment structure, payment amounts, and related issues discussed in this section.

ii. Conceptual Framework for Payment for MDPP Services

In this proposed rule, we are proposing to pay for the set of MDPP services through a performance-based payment methodology that makes periodic performance payments to MDPP suppliers during the MDPP services period. The aggregate of all performance payments constitutes the total performance-based payment amount for the set of MDPP services. As discussed in detail throughout this section, we are proposing a maximum total performance payment amount per beneficiary for the set of MDPP services of $810. Performance payments would be made to MDPP suppliers periodically during the course of a beneficiary’s MDPP services period based upon a number of factors, including the beneficiary’s completion of a specified number of MDPP sessions and the achievement of the required minimum weight loss that is associated with a reduced incidence of type 2 diabetes, rather than individual payments being made upon the furnishing of any service as is typical of payment in the traditional Medicare program.
The aggregate amount of the performance payments proposed in this section would equal the total performance-based payment amount for the set of MDPP services during the MDPP services period, including core sessions, core maintenance sessions, and ongoing maintenance sessions. Even though these performance payments would be made periodically and in amounts that would not be evenly distributed across the course of sessions furnished during the MDPP services period, payment for each session would be included in the total performance-based payment amount. For example, the proposed performance payment of $25 that would be paid to MDPP suppliers upon furnishing the first MDPP core session is relatively large on a per-session basis compared to other attendance-based performance payments (as calculated on a per-session basis) ranging from approximately $3 to $20 made during the MDPP services period. However, the performance payment for the first core session would make payment for some of the MDPP supplier resources used in furnishing the first session, as well as make a partial prospective payment attributable to the MDPP supplier furnishing subsequent sessions.

Once the required minimum weight loss is achieved and the 12-month core services period, described at proposed §410.79(c)(2)(i), concludes, we would make additional 3-month interval performance payments for ongoing maintenance sessions when the required minimum weight loss is maintained, whereas no additional interval performance payments would be made for ongoing maintenance sessions if the required minimum weight loss is not maintained. Finally, when a beneficiary achieves a significant percentage of weight loss, specifically a level of 5 percent (the required minimum weight loss) or 9 percent, we are proposing to make additional performance payments to the MDPP supplier. This proposal would provide performance payments in addition to the performance payments we may have already made for
the previous MDPP sessions furnished to the beneficiary because those sessions resulted in the beneficiary achieving the weight loss performance goal.

In total, based on our consultation with DPP providers holding commercial contracts, review of information related to DPP providers that currently hold or are in the process of obtaining CDC recognition, and comments received on the discussion of the payment structure and payment amounts for the set of MDPP services included in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416), we believe the proposed performance-based payment methodology would pay MDPP suppliers appropriately for the resources used in furnishing MDPP services throughout the MDPP services period. We note that we sought public comment on the payment structure and payment amounts for the set of MDPP services in the July 15, 2016 MDPP proposed rule, and we have used the information provided by commenters in developing the proposed performance-based payments included in this proposed rule.

In this performance-based payment structure, it is important to note that a beneficiary’s performance goals are not considered in the same way for beneficiary coverage and supplier payment during each specific period within the MDPP services period. During the core services period, a beneficiary would not be required to achieve attendance and/or weight loss performance goals for coverage of MDPP services, although a beneficiary would be required to achieve specified performance goals for an MDPP supplier to receive performance payments during this period. In contrast, achieving performance goals would be required for both coverage of MDPP services and performance payments during the ongoing services period.

For example, a supplier is required to offer a minimum of 16 core sessions during the core services period according to §410.79(c)(2)(i) but a beneficiary would not need to achieve an attendance or weight loss performance goal to be eligible for coverage of core maintenance
sessions. However, MDPP supplier performance payments during the core services period would be based on the beneficiary’s achievement of attendance and/or weight loss performance goals. During the ongoing services period, achievement of performance goals would affect both coverage and supplier payment. We note that a beneficiary would need to attend at least 1 core session to initiate the core services period, and attend at least 1 core maintenance session during the final core maintenance session interval to determine whether he or she has achieved the required minimum weight loss to have coverage of ongoing maintenance sessions. Because we are proposing in section III.K.2.d.iii.4 of this proposed rule to make a performance payment for core maintenance sessions only when the beneficiary attends at least 3 sessions within a 3-month interval, it is possible that an MDPP supplier would not be paid a separate performance payment for the second core maintenance session interval, but the beneficiary would still have coverage of the first ongoing maintenance session interval. This would occur if the beneficiary attended only 1 or 2 core maintenance sessions during the second core maintenance session interval and achieved or maintained the required minimum weight loss as measured at 1 of those 2 sessions.

iii. Performance Payments for MDPP Services

(1) Overview of Public Comments on Discussion of Payment for MDPP Services in Prior Rulemaking

In addition to requests for clarification on certain details of the payment structure, such as the timing of beneficiary achievement of weight loss, which are addressed subsequently in this section, commenters on the discussion of payment for MDPP services in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416) expressed a variety of perspectives on the performance-based payment methodology presented in that proposed rule. In general,
commenters urged us to set payment amounts that are sufficient to ensure MDPP supplier participation.

Several commenters recommended that a sustainable payment rate structure should mirror performance-based payment models in the existing employer marketplace. A number of commenters requested that we not tie Medicare payment to weight loss or that we make separate weight loss and attendance payments; that we tie payment to aggregate, rather than individual, beneficiary weight loss; or that we tie payment to other factors besides or in addition to weight loss. Other commenters urged us to provide payment based on sessions furnished by MDPP suppliers rather than basing payment on an individual beneficiary’s success, arguing that the payment structure presented would not be a sustainable model for MDPP suppliers that would expend resources furnishing sessions but would have little influence over beneficiaries’ achievement of attendance and/or weight loss performance goals.

Several commenters requested that we provide information on how the payment rates included in the discussion were determined. Some commenters expressed concern that the magnitude of MDPP payments was not consistent with payments for other similar services.

A number of commenters urged that higher payments be made at the beginning of the MDPP services period to cover program start-up costs, that we decrease supplier financial risk by providing sufficient payment for beneficiaries who do not achieve weight loss performance goals, and that we implement risk-stratification of payments to reduce the risk of MDPP suppliers preferentially seeking to furnish MDPP services to low-risk beneficiaries most likely to achieve weight loss and avoiding high-risk beneficiaries. In addition, several commenters requested that we update the payment rates annually for inflation and the increasing costs experienced by MDPP suppliers.
As discussed in this section, the proposed MDPP payment structure is generally similar to that which was discussed in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416). However, the proposed performance payment amounts for core sessions, core maintenance session 3-month intervals, and ongoing maintenance session 3-month intervals differ somewhat based on our consideration of the comments received in response to the July 15, 2016 MDPP proposed rule in the context of our policy goal to prioritize the achievement and maintenance of the required minimum weight loss that is associated with a reduction in the incidence of type 2 diabetes. In this proposed rule, we are proposing a payment structure for MDPP services that is performance-based in relation to two meaningful performance goals.

First, the proposed payment structure values beneficiary weight loss most significantly. Weight loss is a key indicator of success among individuals enrolled in a DPP due to the strong association between weight loss and reduction in the risk of type 2 diabetes. Second, the proposed payment structure values beneficiary attendance because, in the DPP model test, session attendance was associated with greater weight loss. According to the second year independent evaluation of the DPP model test, those beneficiaries who attended at least 1 core session lost an average of 7.6 pounds, while beneficiaries who attended at least 4 core sessions lost an average of 9 pounds. Body mass index was reduced from 32.9 to 31.5 among Medicare beneficiaries who attended at least 4 core sessions.

In addition to weight loss, we considered linking other criteria such as hemoglobin A1c level to MDPP performance payments, or using aggregate instead of individual weight loss for MDPP payments. However, the MDPP expanded model was determined to meet the statutory requirements for expansion based on the DPP model test, which demonstrated that weight loss was associated with reductions in Medicare expenditures. Although elevated hemoglobin A1c levels were included as part of the beneficiary eligibility criteria in the DPP model test, hemoglobin A1c levels were not evaluated post-intervention in that model. Therefore, we are not proposing to use hemoglobin A1c blood values in the performance-based payment methodology for MDPP services. The use of hemoglobin A1c blood values in the MDPP payment methodology would have incorporated changes in values for which there was no evidence that could be used to support the determination that the MDPP expanded model meets the statutory requirements for expansion. We further note that the CDC does not require post-MDPP services hemoglobin A1c blood values to be determined as part of its 2015 DPRP standards, and we aim to align with the CDC DPRP standards as much as possible. While 5 percent weight loss is considered a performance measure for DPRP recognition, the CDC does not examine pre-post DPP differences in hemoglobin A1c as part of its DPRP standards.

The proposed MDPP payment structure incentivizes MDPP suppliers to prioritize the achievement and maintenance of beneficiary weight loss by furnishing MDPP services, and provides a balance between performance-based payments related to weight loss and session attendance. We do not believe that it would be appropriate for payment to be tied to attendance alone because weight loss is more directly associated with a reduction in the incidence of type 2 diabetes than attendance at MDPP sessions. We further believe that the proposed performance-based payment structure based on individual beneficiary success, rather than average weight loss
across all MDPP beneficiaries who receive MDPP services from an MDPP supplier, maximizes
the focus of MDPP suppliers on the achievement of the performance goals for all beneficiaries,
including those beneficiaries who experience challenges with achieving attendance and/or weight
loss performance goals. Therefore, we do not believe it would be appropriate to use aggregate
beneficiary information (that is, average weight loss) in the proposed performance-based
payment methodology.

(2) Overall Approach to Setting Performance Payment Amounts

We are proposing to establish the rules governing payment for MDPP services at new
§414.84. We note that as discussed in section III.K.2.a. of this proposed rule, we are proposing
that MDPP services may be furnished and payment made under the MDPP expanded model
starting April 1, 2018. Therefore, we are proposing that the effective date of §414.84 would be
April 1, 2018. Only MDPP services furnished on or after April 1, 2018, would be eligible for
payment when all requirements for billing for performance payments for those services are met.

At proposed §414.84(a)(1), we are proposing to define “performance goal” as an
attendance or weight loss goal that an MDPP beneficiary must achieve for an MDPP supplier to
be paid a performance payment. We are proposing to define “performance payment” as a
payment to an MDPP supplier for furnishing certain MDPP services when an MDPP beneficiary
achieves the applicable performance goal. These definitions are used in our proposals for
payment of MDPP services.

To align with the once-per-lifetime policy, we are proposing at §414.84(b) that each
performance payment made based on attendance of a specified number of core sessions, for a
specific 3-month core maintenance or ongoing maintenance interval during the MDPP services
period, or for achieving a weight loss performance goal, is made only once per MDPP beneficiary.

(a) Total Amount and Distribution of Performance Payments Across the Set of MDPP Services

As displayed in Table 27, we are proposing a maximum total performance payment amount per beneficiary for the set of MDPP services of $810. This amount is the aggregate of the maximum performance payments for core sessions, core maintenance sessions, and ongoing maintenance sessions furnished to MDPP beneficiaries who achieve weight loss of at least 9 percent over the 36 months of the MDPP services period. This performance payment amount would be made for a minimum of 46 MDPP sessions required to be offered to the beneficiary in the set of MDPP services. Although CMS would make performance payments to MDPP suppliers at intervals throughout the MDPP services period in varying amounts, payment for each session furnished would be included in the total performance payment amount a supplier was paid for the set of MDPP services.

While we are not proposing that payment for MDPP services utilize a fee-for-service payment methodology, we note that, estimated on a per-session basis, the maximum MDPP payment amount for achievement of all the performance goals would equate to approximately $18 per session. For comparison, Medicare pays under the PFS approximately $10 (excluding physician work and malpractice) for CPT code 98962 (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), a service that may bear some resemblance to an MDPP session furnished by an MDPP supplier, although an MDPP session would be furnished by a coach (not necessarily a health care professional), has a duration of 1 hour, and has no explicit limitation on group size.
However, this estimated per-session MDPP payment amount would result only from the furnishing of MDPP services to those beneficiaries who achieve the highest attendance and weight loss performance goals under the proposed performance-based payment methodology for MDPP services. For beneficiaries who do not achieve the highest performance goals, the estimated per-session MDPP payment amount would generally be significantly lower, with the amount based upon the actual attendance and weight loss performance of the beneficiary. The differences between the estimated MDPP per-session payment amounts and between the MDPP and PFS payment amounts result from the proposed performance-based methodology for MDPP services. We note that under the PFS payments are based on suppliers’ relative resources used to furnish services. On the other hand, we believe that the estimated per-session MDPP payment amounts under our proposal for beneficiaries who achieve specified attendance and weight loss performance goals are appropriate in the context of a performance-based payment methodology for the set of MDPP services that differs from the methodology used under the PFS.

Finally, we note that there are also some administrative costs that MDPP suppliers would bear to enroll in Medicare and ensure compliance with the requirements for furnishing MDPP services. The total MDPP performance payment across all Medicare beneficiaries would provide some payment for the resources that would be used by MDPP suppliers to meet the administrative requirements for furnishing MDPP services.

In terms of the proposed distribution of the maximum total performance payment amount for MDPP services across the types of performance payments, as discussed in detail in sections III.K.2.d.iii.(3) and (4) of this proposed rule and displayed in Table 27, we are proposing that, for those beneficiaries achieving the highest core services period performance goals, approximately
13 percent of the maximum of $810 would be paid for attendance at core sessions during the initial 6 months of the core services period, while approximately 15 percent would be paid for core maintenance sessions during months 7 to 12 of the core services period. We believe that payment of a similar percentage of the maximum total performance payment amount during the initial 6 months of the core services period for beneficiaries who meet attendance performance goals and during months 7 to 12 for beneficiaries who meet both weight loss and attendance performance goals is appropriate to balance performance payment for attendance and weight loss throughout the core services period.

In addition, as discussed in detail in section III.K.2.d.iii.(5) of this proposed rule, we are proposing that approximately 49 percent of the maximum of $810 would be paid for ongoing maintenance sessions over a 24-month period, or 24.5 percent per each 12-month period, for those beneficiaries who maintain the required minimum weight loss. The focus of ongoing maintenance sessions is on maintenance of weight loss that has already been achieved, and there would typically be an established relationship between the MDPP supplier and the MDPP beneficiary during the ongoing services period. Therefore, the totality of MDPP sessions furnished during this 24-month period would result in a slightly lower performance payment per 12-month period than the totality of those sessions furnished when the required minimum weight loss is achieved during the 12 months of the core services period, when 28 percent of the maximum total performance payment amount would be paid.

Finally, due to the importance of weight loss as a meaningful outcome of MDPP services because of its association with a reduction in the incidence of type 2 diabetes, as discussed in detail in section III.K.2.d.iii.(6) of this proposed rule, we are proposing that 23 percent of the maximum total performance payment amount would be paid for weight loss performance
payments to provide additional payments for MDPP sessions that are effective (that is, lead to specified percentages of weight loss). We note that, in the DPP model test, 44.7 percent of participants achieved 5 percent weight loss, which under our proposal would result in a weight loss performance payment of approximately 20 percent of the maximum total performance payment amount. Moreover, according to estimates from CDC’s DPRP, approximately 12 percent of program participants attending at least 2 sessions achieved 9 percent or greater weight loss.

Table 27 summarizes the proposed maximum total amount and distribution of performance payments for the set of MDPP services.

**TABLE 27: Proposed Maximum Total Amount and Distribution of Performance Payments for the Set of MDPP Services**

<table>
<thead>
<tr>
<th>Type of Performance Payment</th>
<th>Maximum Performance Payment for Achieving Attendance and/or Weight-Loss Performance Goals</th>
<th>Percentage of Maximum Total Performance Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core sessions</td>
<td>$105</td>
<td>13%</td>
</tr>
<tr>
<td>Core maintenance session intervals</td>
<td>$120</td>
<td>15%</td>
</tr>
<tr>
<td>Ongoing maintenance session intervals</td>
<td>$400</td>
<td>49%</td>
</tr>
<tr>
<td>Weight loss</td>
<td>$185</td>
<td>23%</td>
</tr>
<tr>
<td><strong>Total performance payment</strong></td>
<td><strong>$810</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

We are inviting public comments on our proposals for the maximum total performance payment amount and the distribution of performance payments for MDPP services across the set of MDPP services.

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14 CDC’s Diabetes Prevention Recognition Program dataset as of March 1, 2017.
(b) Payment Considerations Related to Coverage of MDPP Services for Beneficiaries with Social Risk Factors

We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support play a major role in health. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academies of Sciences, Engineering, and Medicine recently released reports on the issue of accounting for social risk factors in CMS programs.\textsuperscript{15,16} We have previously sought public comment on accounting for social risk factors in CMS programs, primarily on the topics of quality measurement and reporting, such as in the Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models published in the October 1, 2015 \textit{Federal Register} (80 FR 59105, 59109, 59110, and 59113).

In the CY 2017 PFS final rule (81 FR 80466), we acknowledged commenters’ concerns regarding the potential unintended consequences if the MDPP expanded model were to result in low-income or other disadvantaged populations having less access to ongoing maintenance sessions due to their failure to achieve or maintain the weight loss performance goal required for coverage of these sessions. In addition, through listening sessions, stakeholders have provided us with anecdotal information suggesting that racial and ethnic minorities and low socioeconomic status populations lose about 1 percent less weight, on average, than higher socioeconomic groups and non-Hispanic whites.

\textsuperscript{15} Available at https://aspe.hhs.gov/sites/default/files/pdf/253971/ASPESESRTCfull.pdf.
\textsuperscript{16} Available at http://nationalacademies.org/hmd/Reports.aspx?filters=inmeta:activity=Committee+on+Accounting+for+SES+in+Medicare+Payment+Programs.
We are proposing an MDPP payment structure for the set of MDPP services that is similar to the structure presented in the July 15, 2016 MDPP proposed rule (81 FR 46416), where performance payments are tied to attendance at MDPP sessions and/or weight loss. Based on information provided to us by stakeholders, we acknowledge that tying performance payment to a specific threshold of weight loss and/or attendance may make achieving the performance goals required for the highest performance payments and beneficiary eligibility for coverage of ongoing maintenance sessions more challenging for MDPP suppliers furnishing services to individuals with social risk factors. We note that our proposal for beneficiary engagement incentives as discussed in section III.K.2.f. of this proposed rule would provide MDPP suppliers with the flexibility under certain conditions to furnish in-kind patient engagement incentives, such as transportation, to support beneficiaries in achieving the MDPP expanded model performance goals, including session attendance and weight loss. We expect these beneficiary engagement incentives may be helpful to MDPP suppliers furnishing services to beneficiaries, including those with social risk factors that could increase their risk of not achieving the MDPP performance goals.

We are not proposing to risk-adjust MDPP payments for social risk factors or to adopt additional special payment policies to specifically encourage MDPP suppliers to furnish sessions to beneficiaries with social risk factors because, for the MDPP expanded model, we do not believe that such approaches are necessary to ensure access to MDPP services for all beneficiaries. This is because we believe that the proposed performance goals upon which the performance payments for the set of MDPP services would be based, as well as the payment policies that recognize that weight loss is a gradual process that may occur slowly over the 12 months of the core services period, should allow MDPP suppliers sufficient time to work with all
eligible beneficiaries, including beneficiaries with social risk factors, toward achieving the attendance and weight loss performance goals of the MDPP expanded model. However, we may consider proposing additional payment policies for the MDPP expanded model in the future.

We are requesting comments about social risk factors in the context of the set of MDPP services that could inform any future considerations of additional payment policies for the MDPP expanded model. We also are inviting public comments on other types of strategies that we could utilize throughout the testing of the MDPP expanded model to assist MDPP suppliers in providing robust access to MDPP services for beneficiaries with social risk factors, such as learning activities to share best practices among MDPP suppliers in providing the set of MDPP services.

(3) Performance Payments for Core Sessions

The payment structure presented in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416) would have made attendance-based payments of $25 for the first core session, $50 for 4 total core sessions, and $100 for 9 total core sessions. Based on our consideration of information provided in the public comments on that proposed rule and our increased emphasis in the performance payments on the achievement and maintenance of the required minimum weight loss as the outcome of MDPP services, our proposal for the attendance-based performance payments for 4 and 9 core sessions differs from these payment amounts.

We are proposing that an MDPP supplier would be paid a $25 performance payment the first time it furnishes an MDPP session to an MDPP beneficiary as displayed in Table 28. This performance payment would be available once per beneficiary for the beneficiary’s first core session.
We are proposing that an MDPP supplier would be paid the performance payment upon furnishing the first core session to a beneficiary who initiates the MDPP services period, regardless of whether the MDPP supplier qualifies for any of the additional performance payments for that beneficiary. As we are proposing in the sections that follow, additional performance payments would depend upon the beneficiary’s achievement of the performance goals for attendance and/or weight loss. We believe that making the first performance payment based on beneficiary attendance at the first core session is appropriate because the MDPP supplier would use significant resources to furnish the first session, including collecting administrative information on the beneficiary who is not already known to the supplier, regardless of whether the beneficiary goes on to receive further MDPP services from that supplier.

On a per-session basis, the performance payment for the first MDPP core session would be the highest performance payment amount for any core session during the core services period. Of note, the first core session performance payment also provides some payment for MDPP supplier activities to encourage the beneficiary’s attendance at additional core sessions following the first session. Such supplier activities could include sending electronic messages or making reminder phone calls about upcoming sessions or providing transportation to the next session under the beneficiary engagement incentives policy proposed in section III.K.2.f. of this proposed rule. It is only through attendance at the first core session with an MDPP supplier that a beneficiary initiates the MDPP services period and has the potential to achieve weight loss through receiving MDPP services.

Further, we are proposing that suppliers would be paid a performance payment for the interval (which we are referring to in this proposed rule as an “interval performance payment” to
distinguish it from other performance payments, such as the performance payment upon an MDPP beneficiary’s achievement of the required minimum weight loss, that do not require attendance at multiple sessions) upon a beneficiary’s attendance at 4 total core sessions, and again upon a beneficiary’s attendance at 9 total core sessions—that is, attendance of 5 more core sessions after having attended his or her first 4. We are proposing an interval performance payment of $30 upon a beneficiary attending 4 core sessions and an interval performance payment of $50 upon a beneficiary attending 9 core sessions as displayed in Table 28. Although an MDPP supplier must offer at least 16 core sessions to a beneficiary during the initial 6 months of the MDPP core services period, we are not proposing any other interval performance payment for the core sessions after the performance payment for attendance at 9 core sessions. We note that while these proposed payment amounts are somewhat lower than the payment amounts for these milestones presented in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416), they follow a similar pattern of a higher payment amount associated with attendance at a larger cumulative number of core sessions to provide a significant financial incentive for MDPP suppliers to encourage MDPP beneficiary attendance at core sessions in the first 6 months of the core services period.

On a per-session basis, the payments for attendance at 4 total core sessions and 9 total core sessions would be approximately $10 and $4 to $10, respectively, depending upon the number of sessions attended by the beneficiary beyond the 9 required for the second interval performance payment up to the maximum of 16 core sessions that must be offered to the beneficiary by the MDPP supplier during the initial 6 months of the MDPP core services period. Because the performance payments for core sessions would be based solely on the achievement of attendance performance goals, we believe these per-session performance payment amounts
that are lower than the proposed performance payment amount for the first core session are still appropriate because we expect that fewer MDPP supplier resources would be used to furnish sessions to beneficiaries with whom the MDPP supplier has an established relationship. The per-session payment amounts for core sessions are set based on attendance at these sessions, which is associated with ultimate achievement of the required minimum weight loss.

We are proposing to make the first interval performance payment for core sessions when the beneficiary has attended 4 core sessions for the following reasons. First, beneficiary attendance at 4 core sessions was a significant attendance milestone in the evaluation of the DPP model test, which provided evidence that meeting this milestone is tied to weight loss outcomes. According to the second year independent evaluation of the DPP model test, those beneficiaries who attended at least 1 core session lost an average of 7.6 pounds while beneficiaries who attended at least 4 core sessions lost an average of 9 pounds. BMI was reduced from 32.9 to 31.5 among Medicare beneficiaries who attended at least 4 core sessions.

Second, in examining CDC’s DPRP participant trend data, we found that a higher percentage of participants drop out after 3 core sessions as compared to those who drop out after 4 core sessions, meaning that if a beneficiary completes the 4th core session, he or she is more likely to remain in the DPP for the 12-month program. Therefore, we believe making the first interval performance payment after beneficiary attendance at 4 core sessions would be appropriate.

We are proposing to make the second interval performance payment when the beneficiary has attended 9 core sessions because attending a higher amount of sessions in the initial 6 months

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18 CDC’s Diabetes Prevention Recognition Program dataset as of March 1, 2017.
of the MDPP core services period, beginning at session 9, has been shown to greatly improve weight loss outcomes. Specifically, according to CDC data, there is a 125 percent increase in weight loss comparing beneficiaries who attend 4 to 8 sessions (1.6 percent weight loss on average) and beneficiaries who attend 9 to 16 sessions (3.6 percent weight loss on average).19 Therefore, we believe that attendance at 9 sessions reflects clinically meaningful attendance at core sessions and would provide an incentive to MDPP suppliers to encourage beneficiaries to continue into the second 6 months of the MDPP core services period, which is when the 5 percent weight loss from baseline is usually achieved or exceeded. Additionally, 9 is the number of core sessions, on average, that a participant must attend in CDC’s National DPP in the first 6 months for a CDC-recognized organization to achieve full CDC recognition.

MDPP suppliers would be paid these performance payments when beneficiaries achieve these core session attendance performance goals, regardless of weight loss. Although we are proposing to base performance payments during the MDPP services period substantially on weight loss, which is directly associated with a significant decrease in the incidence of type 2 diabetes, we recognize that weight loss is a gradual process and that MDPP suppliers utilize resources to furnish MDPP services during the period of time when the beneficiary is losing weight. Therefore, we are proposing that performance payments for beneficiary attendance at core sessions during the first 6 months of the core services period be based on attendance only.

The maximum total performance payment to MDPP suppliers for furnishing MDPP core sessions would be $105 per beneficiary, as displayed in Table 28.

19CDC’s Diabetes Prevention Recognition Program dataset as of February 28, 2017.
We considered alternatives to this proposed payment structure for core sessions, such as making higher payments for attendance at the earlier sessions to provide MDPP suppliers with additional funds for the resources necessary for start-up of the MDPP expanded model. Although we understand that there are some up-front supplier costs associated with implementing the MDPP expanded model, we believe these costs would disproportionately be related to start-up and not generally be ongoing costs borne by the MDPP supplier. In addition, because we expect that many MDPP suppliers are currently offering DPPs through contracts with commercial payers, MDPP suppliers may be able to minimize start-up costs by relying on their relevant experience with offering other DPPs. Finally, we believe that our proposal for payment of MDPP core sessions already includes substantial payment for session attendance early in a beneficiary’s participation with the MDPP supplier, considering that MDPP suppliers would be paid an initial $25 performance payment for the first core session attended by the beneficiary and would then be paid performance payments for beneficiary attendance of up to 9 core sessions, regardless of weight loss. We believe that increasing the initial payments for attendance at MDPP sessions would shift the nature of the payment for the set of MDPP services from a performance-based structure based on a balance of attendance and weight loss considerations toward a payment structure that is based on attendance at each session furnished.

### TABLE 28: Proposed Attendance-Based Performance Payments for MDPP Core Sessions

<table>
<thead>
<tr>
<th>Performance Goal</th>
<th>Attendance-Based Performance Payment Per Beneficiary</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st core session attended (performance payment)</td>
<td>$25</td>
</tr>
<tr>
<td>4 total core sessions attended (interval performance payment)</td>
<td>$30</td>
</tr>
<tr>
<td>9 total core sessions attended (interval performance payment)</td>
<td>$50</td>
</tr>
<tr>
<td>Maximum total performance payment for core sessions</td>
<td>$105</td>
</tr>
</tbody>
</table>
The proposed attendance-based performance payments for MDPP core sessions are included at proposed §414.84(b)(1), (2), and (3). We are inviting public comments on these proposals. We also are inviting public comments on the alternative considered.

(4) Performance Payments for Core Maintenance Session Intervals

We are proposing that performance payments for core maintenance sessions would be tied to the beneficiary’s achievement of attendance and weight loss performance goals during a core maintenance session interval. A core maintenance session interval, as we are proposing to define it at §410.79(b), means one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers at least one core maintenance session per month to an MDPP beneficiary.

The payment structure presented in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416) would have required the MDPP beneficiary to attend 3 core maintenance sessions and achieve or maintain a minimum 5 percent weight loss for a $45 payment to be made to an MDPP supplier for the core maintenance session interval. If 5 percent weight loss was not achieved or maintained during the core maintenance session interval, no separate performance payment would be made. MDPP suppliers would still have been required to offer (and furnish if the beneficiary attended) MDPP services during core maintenance intervals to beneficiaries regardless of weight loss. Based on our consideration of information provided in the public comments on that proposed rule and our increased emphasis in the performance payments on the achievement and maintenance of the required minimum weight loss as the outcome of MDPP services, our proposal for the performance payments for core maintenance sessions differs from
the payment amounts included in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416).

For the MDPP expanded model, we are proposing performance payments amounts for core maintenance session intervals that value achievement of both session attendance and the required minimum weight loss, with an emphasis on achieving the weight loss performance goal. We are proposing that an MDPP supplier would be paid a performance payment for a core maintenance session interval if a beneficiary achieves the performance goal of attending at least 3 core maintenance sessions during the interval. The specific performance payment amount would be determined by whether the beneficiary has also achieved or maintained the required minimum weight loss within the interval. The achievement or maintenance of the required minimum weight loss within the 3-month core maintenance session interval would be determined based on a measurement taken in-person during any 1 session within that 3-month interval. We are proposing that MDPP suppliers would be paid a performance payment for no more than two core maintenance session intervals for each MDPP beneficiary.

As discussed previously, we recognize that weight loss is a process that may still be ongoing for some beneficiaries during the final months of the core services period. According to an analysis of participant data from CDC’s DPRP, the longer a participant remains in the lifestyle change program, the greater his or her average weight loss achieved.\textsuperscript{20} Findings indicate that it takes an average of 17 DPP sessions attended to exceed the required minimum weight loss, and the 9 percent or greater weight loss goal is more likely to be achieved upon attending 19 sessions on average. This average number of sessions exceeds the 16 core sessions that must be offered to the MDPP beneficiary during the first 6 months of the MDPP services period and

\textsuperscript{20} CDC’s Diabetes Prevention Recognition Program dataset as of March 1, 2017.
emphasizes the importance of core maintenance sessions to achievement of meaningful weight loss goals.

Of further note, the National DPP’s core maintenance sessions were developed based on results from the original 2002 DPP Randomized Control Trial and CDC’s DPRP standards were developed with this science in mind.\(^{21}\) Core maintenance sessions are integral for the expected reduction in the incidence of type 2 diabetes to be experienced by MDPP beneficiaries. These findings were recently confirmed in a literature review on combined diet and physical activity programs to prevent type 2 diabetes conducted by the Community Preventive Services Task Force that reiterated the year-long intensity and duration of the National DPP.\(^{22}\)

Therefore, we believe that providing no performance payment to MDPP suppliers for furnishing core maintenance sessions to beneficiaries who have not achieved the required minimum weight loss prior to or during months 7 to 12 of the core services period could reduce the opportunity for MDPP beneficiaries to achieve the weight loss performance goal. Such a payment methodology could reduce the likelihood that MDPP suppliers would continue to work to engage beneficiaries in the weight loss process if those beneficiaries had not achieved the required minimum weigh loss after completion of the initial 6 months of the MDPP core services period. We note that, as finalized in the CY 2017 PFS final rule (81 FR 80459), suppliers must offer a minimum of 1 core maintenance session per month in months 7 to 12 of the core services period to eligible beneficiaries, regardless of the beneficiary’s weight loss. We believe that it is possible for some beneficiaries to have achieved the required minimum weight loss performance goal by the time the core sessions have been completed, and we want to incentivize MDPP beneficiaries...


\(^{22}\) Available at http://www.thecommunityguide.org/diabetes/combineddietandpa.html.
suppliers to work toward the weight loss performance goal in that timeframe. However, we believe that it is also appropriate to place some value on achieving attendance performance goals alone through performance payments for core maintenance session intervals so that MDPP suppliers continue to work to engage all beneficiaries in striving to achieve the required minimum weight loss performance goal.

As discussed in section III.K.2.d.iii.(2)(a) of this proposed rule, we are proposing that the maximum total performance payment for MDPP core maintenance sessions would be $120 for beneficiaries who achieve both the attendance and weight loss performance goals during months 7 to 12 of the core services period. Specifically, we are proposing to pay MDPP suppliers $60 for a core maintenance session interval if a beneficiary attends 3 sessions and achieves or maintains the required minimum weight loss during that interval, and to pay MDPP suppliers $10 for a core maintenance session interval if the beneficiary attends 3 sessions but does not achieve or maintain the required minimum weight loss during that core maintenance session interval.

As compared to the payment amounts with and without achievement or maintenance of the required minimum weight loss that were presented for core maintenance session intervals in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416), these payment amounts are both higher. As discussed previously in this section, we believe it is appropriate in months 7 to 12 of the core services period to provide some performance payment for achievement of attendance performance goals even if the required minimum weight loss is not achieved, in order to provide the greatest opportunity for beneficiaries to achieve the required minimum weight loss over the full core services period. In addition, we are proposing a higher payment amount for core maintenance session intervals with achievement or maintenance of the required minimum
weight loss to recognize that achievement and maintenance of the required minimum weight loss are necessary for the reduced incidence of type 2 diabetes and to encourage MDPP suppliers to work to engage beneficiaries in achieving weight loss and sustaining their weight loss over time.

Proposed performance payments for the core maintenance session intervals are displayed in Table 29. On a per-session basis, these payments would be approximately $20 and $3, respectively. While both of these payment amounts provide payment to MDPP suppliers for the resources involved with furnishing core maintenance sessions, we believe the relatively high per-session performance payment of $20 in comparison to the per-session performance payment amounts for core sessions is appropriate due to the achievement or maintenance of both the required minimum weight loss and beneficiary attendance at core maintenance sessions, as compared to core sessions where the performance payment is based solely on attendance. On the other hand, we believe that the relatively low per-session payment amount in our core maintenance session interval performance payment proposal for core maintenance sessions for those beneficiaries who do not achieve the weight loss performance goal, while providing some performance payment for attendance at core maintenance sessions by beneficiaries still working to achieve the required minimum weight loss, is appropriate because these sessions have not yet resulted in those beneficiaries achieving the weight loss performance goal.
TABLE 29: Proposed Performance Payments for Core Maintenance Session Intervals

<table>
<thead>
<tr>
<th>Performance Goal</th>
<th>Performance Payment Per Beneficiary (with achievement or maintenance of required minimum weight loss)</th>
<th>Performance Payment Per Beneficiary (without achievement or maintenance of required minimum weight loss)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 sessions attended in first core maintenance session interval (months 7-9 of the MDPP core services period)</td>
<td>$60</td>
<td>$10</td>
</tr>
<tr>
<td>3 sessions attended in second core maintenance session interval (months 10-12 of the MDPP core services period)</td>
<td>$60</td>
<td>$10</td>
</tr>
<tr>
<td>Maximum total performance payment for core maintenance session intervals (two consecutive 3-month intervals over months 7-12 of the MDPP core services period)</td>
<td>$120</td>
<td>$20</td>
</tr>
</tbody>
</table>

The proposed core maintenance session interval performance payments for core maintenance sessions are included at proposed §414.84(b)(4). We are inviting public comments on these proposals.

(5) Performance Payments for Ongoing Maintenance Session Intervals

Similar to our proposal for the payment of core maintenance session intervals described previously, we are proposing to make performance payments to MDPP suppliers for 3-month ongoing maintenance session intervals. This payment would be made when suppliers furnish ongoing maintenance sessions during the 24 months of the ongoing services period after the 12-month MDPP core services period ends. We are proposing that an MDPP supplier would be paid a performance payment for an ongoing maintenance session interval if an MDPP beneficiary achieves the performance goals of attending at least 3 ongoing maintenance sessions and maintaining the required minimum weight loss from baseline measured in person during a
session at least once within that interval. Under this proposal, an MDPP supplier would not be paid a performance payment unless the beneficiary has achieved these both of these performance goals within that 3-month interval. An ongoing maintenance session interval, as we are proposing to define it at §410.79(b), means one of the up to eight consecutive 3-month time periods during the ongoing services period, during which an MDPP supplier offers at least one ongoing maintenance session to an MDPP beneficiary per month.

The payment structure presented in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416) would have required the MDPP beneficiary to attend 3 ongoing maintenance sessions and maintain the required minimum weight loss for a $45 payment to be made to an MDPP supplier for the ongoing maintenance session interval. Based on our consideration of information provided in the public comments on that proposed rule and our increased emphasis in the performance payments on the achievement and maintenance of weight loss as the outcome of MDPP services, our proposal for the performance payment for ongoing maintenance session intervals differs from that payment amount.

We are proposing that MDPP suppliers could be paid up to 8 performance payments of $50 each for ongoing maintenance session intervals. Just like the other proposals for performance payments, we are proposing this payment in CY 2018 dollars to ensure consistency in calendar year dollars among performance payments for a given calendar year. However, we note that no ongoing maintenance session interval payments, available only for intervals in the ongoing services period during months 13 through 36 of an MDPP beneficiary’s MDPP services period, would be made in CY 2018 based on our proposal in section III.K.2.a. of this proposed rule that MDPP services be available on April 1, 2018. Under this proposal, MDPP services would only be available for 9 months of CY 2018 so no MDPP beneficiaries would attend
ongoing maintenance sessions in CY 2018. The first ongoing maintenance session interval performance payments would be made in CY 2019 and would equal $50 adjusted by the percent change in the Consumer Price Index for All Urban Consumers (CPI-U) (U.S. city average) for the 12-month period ending June 30th, 2018, as discussed in section III.K.2.d.iii.(9) of this proposed rule.

This proposed payment amount is somewhat higher than the potential payment discussed in the July 15, 2016 MDPP proposed rule (81 FR 46415 through 46416) to recognize that maintenance of the required minimum weight loss is necessary for the reduced incidence of type 2 diabetes and to encourage MDPP suppliers to work to engage beneficiaries in sustaining their weight loss over time. The maximum total performance payment for MDPP ongoing maintenance sessions would be $400, as displayed in Table 30. On a per-session basis, this payment would be approximately $17, which we believe is appropriate for MDPP suppliers that furnish ongoing maintenance sessions to beneficiaries who maintain the required minimum weight loss during ongoing maintenance session interval. We note that this per-session payment amount would be somewhat lower than the $20 per-session payment amount included in the core maintenance session interval performance payment for beneficiaries who achieve attendance and weight loss performance goals during the 3-month intervals in months 7 to 12 of the MDPP core services period. Like the proposed performance payment for core maintenance session intervals, the proposed performance payment for ongoing maintenance session intervals values both attendance and weight loss. However, during core maintenance session intervals it is likely that the required minimum weight loss would first be achieved, and we believe that a somewhat higher per-session payment amount is appropriate under these circumstances. In contrast, we believe that a somewhat lower per-session payment amount for ongoing maintenance sessions
during intervals where the required minimum weight loss is maintained, rather achieved, is appropriate.

We considered an alternative policy in which an MDPP supplier would receive a payment for an ongoing maintenance session interval so long as the beneficiary attended at least 1 ongoing maintenance session during the interval and maintained the required minimum loss. In this scenario, we considered that the MDPP supplier would still be required to offer at least 2 additional ongoing maintenance sessions (at least one per month) to the beneficiary over the 3-month interval. However, we believe that the goal of ongoing maintenance sessions is to promote both sustained beneficiary engagement and weight loss and, therefore, we believe that ongoing maintenance session interval performance payments should be tied to achieving both attendance and weight loss performance goals.

The proposed payment policy also would align with the service limitations for ongoing maintenance sessions at §410.79(c)(1)(iii) in that beneficiaries also would be required to attend all 3 sessions within a given ongoing maintenance session 3-month interval to be covered for the subsequent 3-month interval. We note that the proposed coverage and payment policies are aligned for ongoing maintenance session intervals, where attendance at 3 sessions within an interval is required for a performance payment as well as for coverage of ongoing maintenance sessions in the next interval. In contrast, MDPP suppliers are required to offer core maintenance sessions in both core maintenance session intervals for all beneficiaries, regardless of a beneficiary’s attendance at core maintenance sessions, although attendance is required for a performance payment to be made for the core maintenance session interval.
TABLE 30: Proposed Performance Payments for Ongoing Maintenance Session Intervals

<table>
<thead>
<tr>
<th>Performance Goal</th>
<th>Performance Payment Per Beneficiary (with maintenance of the required minimum weight loss)</th>
<th>Performance Payment Per Beneficiary (without maintenance of the required minimum weight loss)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 sessions attended in 1 ongoing maintenance session interval</td>
<td>$50</td>
<td>$0</td>
</tr>
<tr>
<td>Maximum total performance payment for ongoing maintenance session intervals (8 consecutive 3-month intervals over months 13-36 of the MDPP ongoing services period)</td>
<td>$400</td>
<td>*$0 to $350</td>
</tr>
</tbody>
</table>

* = The specific payment amount depends on whether the beneficiary has coverage of 1 to 7 ongoing maintenance session intervals, as well as whether the beneficiary meets the performance goals for the performance payment for that ongoing maintenance session interval.

The proposed ongoing maintenance session interval performance payments for ongoing maintenance sessions are included at proposed §414.84(b)(5). We are inviting public comments on these proposals. We also are inviting public comments on the alternative considered.

(6) Weight Loss Performance Payments

We are proposing that if a beneficiary achieves the required minimum weight loss measured at any session attended during the core services period, an MDPP supplier would be paid the weight loss performance payment of $160 displayed in Table 31. As discussed in section III.K.2.d.iii.(2)(a) of this proposed rule, we are proposing that 23 percent of the maximum total performance payment amount for the set of MDPP services would be paid for the achievement of weight loss, regardless of session attendance, because weight loss is the most important outcome for the MDPP expanded model. The proposed performance payment of $160 for the required minimum weight loss, which constitutes approximately 90 percent of the maximum total weight loss performance payment, was set to be the large majority of the
available weight loss performance payment based on the strong evidence for the association of the required minimum weight loss with a reduction in the incidence of type 2 diabetes.

We note that this association is evidenced by the CDC’s National DPP, which is based on the 2002 DPP Randomized Control Trial and follow-up efficacy trials. All of the trials found that the greater the intensity and duration of the diabetes prevention program—with 1 year being the most effective program “dose”—the greater the reduction in the incidence of type 2 diabetes. Specially, persons at high-risk for type 2 diabetes who participated in a year-long lifestyle change program, focused on modest weight loss (5-7 percent), experienced a 58 percent lower incidence of type 2 diabetes than those who did not receive the lifestyle intervention. The DPP Randomized Control Trial, as well as the DPP model test, involved the provision of 16 weekly core sessions and 6 monthly core maintenance sessions (all approximately 1 hour in length), similar to the set of core services in the MDPP expanded model. We recognize that not all beneficiaries would be able to achieve the required minimum weight loss within the first 6 months, which is the period when core sessions are furnished. Therefore, we believe that our proposed policy for payment of the performance payment upon achievement of the required minimum weight loss any time during the 12 months of the MDPP core services period would allow MDPP suppliers the greatest flexibility to work throughout the full MDPP core services period with beneficiaries who face difficulty in achieving this weight loss performance goal.

We also are proposing that, in addition to the weight loss performance payment for the required minimum weight loss, an MDPP supplier would be paid an additional weight loss performance payment of $25 if the beneficiary achieves at least 9 percent weight loss from his or her baseline weight at any time during the MDPP services period as displayed in Table 31. We

are proposing this additional weight loss performance payment based on information from stakeholders that commercial payers paying for DPPs frequently include an incentive payment for 9 percent weight loss as an incentive to try to encourage greater and/or continued weight loss and behavior change. We believe that making an additional weight loss performance payment for 9 percent weight loss at any time during the MDPP services period would provide an additional incentive for MDPP suppliers to continue weight loss efforts with beneficiaries, especially during the ongoing services period, which may extend for a period of up to 24 months.

We are proposing that MDPP suppliers may submit claims for these weight loss performance payments on the date when the beneficiary first reaches the required minimum or 9 percent weight loss, as measured in person during a session, respectively, and each weight loss performance payment would be paid to only one supplier and only once per beneficiary. In the unusual circumstance where the beneficiary achieved 9 percent weight loss as the first weight loss change measured from baseline, the MDPP supplier could bill and be paid both the 5 percent and 9 percent weight loss performance payments.

<table>
<thead>
<tr>
<th>Performance Goal</th>
<th>Performance Payment Per Beneficiary</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 percent weight loss (required minimum weight loss)</td>
<td>$160</td>
</tr>
<tr>
<td>9 percent weight loss</td>
<td>$25</td>
</tr>
<tr>
<td>Maximum total performance payment for weight loss</td>
<td>$185</td>
</tr>
</tbody>
</table>

The proposed weight loss performance payments are included at proposed §414.84(b)(6) and (7). We are inviting public comments on these proposals.

(7) Summary Table of Performance Payments for the Set of MDPP Services

In summary, for furnishing MDPP services during the MDPP services period, we are proposing that MDPP suppliers could be paid a minimum of $25 per beneficiary (if the
beneficiary attends the first core session) and a maximum total of $810 per beneficiary (if the beneficiary achieves all performance goals, maintains eligibility for 36 months, and does not change MDPP suppliers). Table 32 summarizes all of the proposed performance payments for the set of MDPP services that are discussed in sections III.K.2.d.iii.(3) through (6) of this proposed rule.

**TABLE 32: Proposed Performance Payments for the Set of MDPP Services**

<table>
<thead>
<tr>
<th>Performance Goal</th>
<th>Performance Payment Per Beneficiary (with the required minimum weight loss)</th>
<th>Performance Payment Per Beneficiary (without the required minimum weight loss)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st core session attended</td>
<td>$25</td>
<td></td>
</tr>
<tr>
<td>4 total core sessions attended</td>
<td>$30</td>
<td></td>
</tr>
<tr>
<td>9 total core sessions attended</td>
<td>$50</td>
<td></td>
</tr>
<tr>
<td>3 sessions attended in first core maintenance session interval (months 7-9 of the MDPP core services period)</td>
<td>*$60</td>
<td>$10</td>
</tr>
<tr>
<td>3 sessions attended in second core maintenance session interval (months 10-12 of the MDPP core services period)</td>
<td>*$60</td>
<td>$10</td>
</tr>
<tr>
<td>5 percent weight loss achieved</td>
<td>$160</td>
<td>$0</td>
</tr>
<tr>
<td>9 percent weight loss achieved</td>
<td>$25</td>
<td>$0</td>
</tr>
<tr>
<td>3 sessions attended in ongoing maintenance session interval (eight consecutive 3-month intervals over months 13-36 of the MDPP ongoing services period)</td>
<td>*$50</td>
<td>**$0</td>
</tr>
<tr>
<td>Total performance payment</td>
<td>$810</td>
<td>$125</td>
</tr>
</tbody>
</table>
* = The required minimum weight loss from baseline must be achieved or maintained during the core maintenance session 3-month interval or maintained during the ongoing maintenance session 3-month interval.

** = A beneficiary attends at least 1 core session during the core services period to initiate the MDPP services period; must attend at least 1 session during the final core maintenance session 3-month interval; and must achieve or maintain the required minimum weight loss at least once during the final core maintenance session 3-month interval to have coverage of the first ongoing maintenance session interval. Then, a beneficiary must attend at least 3 sessions and maintain the required minimum weight loss at least once during an ongoing maintenance session 3-month interval to have coverage of the next ongoing maintenance session interval.

(8) Considerations Related to Potential Future Geographic Adjustment of MDPP Payments

Although Medicare is a national program, it frequently adjusts fee-for-service payments to hospitals, physicians, and other providers and suppliers according to the geographic locations in which they furnish services. These adjustments generally account for differences in the relative costs of doing business in different geographic areas compared to the national average. For example, section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. This adjustment factor for hospitals is the wage index, and we currently define hospital geographic areas (labor market areas) based on the definitions of Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget. Similarly, a geographic adjustment is also made for services paid under the PFS, and a geographic practice cost index (GPCI) has been established for every Medicare PFS payment locality, many of which are statewide, for each of the three components of a service’s relative value units (that is, the relative value units for work, practice expense, and malpractice).

We are proposing to make performance-based payments to MDPP suppliers in intervals based on achievement of performance goals, rather than fee-for-service payments for individual
services furnished. While we intend for those performance payments to make payment to MDPP suppliers for MDPP services that involve the use of supplier resources, we are unsure if there is notable variation in the relative costs of furnishing MDPP services among geographic areas. Because the DPP model test was carried out in only eight States, we do not have the data to determine whether there are geographic differences nationwide. In addition, because a substantial portion of the proposed MDPP performance payments are based on the beneficiary’s achievement of weight loss performance goals, we are uncertain about the appropriateness of geographically adjusting such performance-based payments.

Therefore, we are not proposing geographic adjustment of performance payments for MDPP services. However, we are inviting public comments on issues related to geographic adjustment of payment for MDPP services in the context of the MDPP performance-based payment methodology, including appropriate sources of information for determining any geographic cost differences. We may consider proposing additional payment policies for the MDPP expanded model in the future. We request that commenters submitting information on these issues provide justification, including any relevant analysis, to support any suggestions regarding potential future geographic adjustment of performance-based payments for MDPP services.

(9) Updating MDPP Payment Amounts

To account for inflation, we are proposing to update MDPP payment amounts annually based on the CPI-U). The CPI-U is a measure of the average change over time in prices paid for a market basket of consumer goods and services, and is a measure of economy-wide inflation. There are no statutory requirements for the update factor for payments for MDPP services so there is no requirement that a productivity adjustment be applied to the MDPP services update.
factor as there are for certain other Medicare-covered items and services where prices are updated by the CPI-U, such as the Clinical Laboratory Fee Schedule; Durable Medical Equipment, Prosthetics/Orthotics, and Supplies Fee Schedule; Ambulance Fee Schedule; and Ambulatory Surgical Center payment system.

We considered using other indices such as the Medicare Economic Index (MEI) to update the MDPP payment amounts. The MEI measures price changes in the inputs required to operate a self-employed physician practice. We do not believe that the MEI would be appropriate to update MDPP payment amounts because MDPP suppliers are not similar to self-employed physician practices. We note that the CPI-U by definition is an economy-wide measure of inflation and, therefore, in the absence of an appropriate specific index for MDPP services, we believe the CPI-U to be the most technically appropriate index available to update payments for MDPP services. We further note that the CPI-U is used to update Medicare payments for other Medicare-covered items and services, such as ambulance, clinical laboratory, and ambulatory surgical center services.

We are proposing to update MDPP performance payments and the bridge payment (a proposed one-time payment to an MDPP supplier for furnishing its first session to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier as discussed in detail in section III.K.2.d.v. of this proposed rule) that may be paid to MDPP suppliers in the following manner:

- Beginning in CY 2019 and each year forward, the performance payment and bridge payment amounts will be adjusted by the 12-month percent change in the CPI-U (U.S. city average) for the period ending June 30th of the year preceding the update year. The percent change update will be calculated based on the level of precision of the index as published by the
Bureau of Labor Statistics and applied based on one decimal place of precision. The annual MDPP services payment update will be published by CMS transmittal.

The proposed methodology to update MDPP performance payments and the bridge payment is included at proposed §414.84(d). We are inviting public comments on this proposal.

(10) MDPP Supplier Billing and Payment for MDPP Services

(a) Payment for MDPP Services on an Assignment-Related Basis

We are proposing that performance payments and bridge payments to MDPP suppliers for MDPP services would be made only on an assignment-related basis in accordance with §424.55. As described in Chapter 1, Section 30.3 of the Medicare Claims Processing Manual, CMS identifies a number of supplier and practitioner types who furnish services under the Medicare program and who are required to accept assignment for all Medicare claims for their services. This means that they must accept the Medicare allowed amount as payment in full for their services, regardless of whether the supplier is a participating or non-participating provider in the Medicare program. In these circumstances, the beneficiary’s liability is limited to any applicable deductible plus the 20 percent coinsurance if coinsurance applies to the service. CMS currently mandates assignment for claims from multiple types of suppliers and practitioners, including clinical diagnostic laboratory services and physician lab services; physician services to individuals dually entitled to Medicare and Medicaid; and services of physician assistants, nurse practitioners, clinical nurse specialists, nurse midwives, certified registered nurse anesthetists, clinical psychologists, clinical social workers, registered dietitians/nutritionists, anesthesiologist assistants, and mass immunization roster billers. The beneficiary (or the person authorized to request payment on the beneficiary’s behalf) is not required to assign the claim to the supplier in

order for an assignment to be effective, and when these claims are inadvertently submitted as unassigned, Medicare Administrative Contractors (MACs) process them as assigned.

Consistent with our established requirements for these other types of suppliers, some of whom are similar to MDPP suppliers in that they furnish a limited breadth of Medicare-covered services, we believe it would be appropriate to require all MDPP suppliers, whether they are participating or not participating in Medicare, to accept assignment. We also believe that making performance payments for MDPP services solely on an assignment-related basis is the most appropriate methodology, given the performance-based MDPP payment methodology which is based on the achievement of weight loss and/or attendance performance goals and not based on the MDPP supplier resource expended to furnish individual MDPP services. We further note that as finalized in the CY 2017 PFS final rule (81 FR 80464), MDPP services are additional preventive services under section 1861(ddd) of the Act and, therefore, consistent with section 1833(a)(1)(W) of the Act, are not subject to the Medicare Part B coinsurance or deductible. Under our proposal Medicare would pay 100 percent of the Medicare allowed charge for MDPP services furnished to MDPP beneficiaries, and a beneficiary would have no liability for covered MDPP services. MDPP suppliers would be required to accept the Medicare allowed charge as payment in full and would not be able to bill or collect from the beneficiary any amount.

Finally, to minimize the potential administrative burden on beneficiaries related to payment for MDPP services on an assignment-related basis, we are proposing that for purposes of claims for services submitted by an MDDP supplier, Medicare would deem such claims to have been assigned by the beneficiary (or the person authorized to request payment on the beneficiary's behalf) and the assignment accepted by the MDDP supplier. This proposed treatment of claims from MDPP suppliers in new §424.55(d) is consistent with the current
exception in §424.55(c) regarding payment to a supplier which specifies that when payment under the Act can only be made on an assignment-related basis or when payment is for services furnished by a participating physician or supplier, the beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective.

The proposed assignment-related basis for performance payments and bridge payments MDPP suppliers is included at proposed §414.84(b) and (c). The proposal to not require the beneficiary to assign the claim for MDPP services to the MDPP supplier in order for assignment to be effective is included at proposed §424.55(d). We are inviting comments on these proposals.

(b) Requirements for Payment of Bridge Payments and Performance Payments

MDPP suppliers may only submit claims for a performance payment or bridge payment for MDPP services when all of the proposed requirements for the payment are met. Claims for services that do not meet these requirements will not be paid. In accordance with §424.80, MDPP suppliers are reminded that there are exceptions to the prohibition of reassignment of claims by suppliers for certain arrangements provided the applicable requirements are met. Of specific note, Medicare may pay an agent who furnishes billing and collection services to the supplier if the conditions of §424.80(b)(5) are met.

Proposed requirements for performance payments and the bridge payment include that the MDPP services were furnished to a beneficiary eligible for MDPP services as specified at §410.79(c) and that the MDPP supplier complies with all applicable enrollment and program requirements. In addition, the MDPP services must be furnished by an eligible coach on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end


date, and the MDPP supplier must submit the National Provider Identifier (NPI) of the coach on MDPP claims. We describe additional details on how eligible coach information would be processed in section III.K.2.d.iii.(10)(d) of this proposed rule. All specific additional proposed requirements for the performance payment or bridge payment, as discussed in sections III.K.2.d.iii.(3) through (6) and III.K.2.d.v. of this proposed rule, must also be met.

In order to submit a claim for a performance payment under the MDPP expanded model, the billing supplier must have documentation in the beneficiary’s MDPP record, as specified in proposed §424.205(g), that all requirements for the payment, including the achievement of the performance goal(s) applicable to the performance payment, have been met. We note that the billing supplier’s MDPP record for the beneficiary may include a copy of the beneficiary’s MDPP record from a previous MDPP supplier that has been provided to the billing supplier at the request of the MDPP beneficiary. For purposes of an MDPP supplier submitting a claim for an interval performance payment based on attendance at more than one session, this copy of the MDPP record from the previously MDPP supplier may be used as part of the billing supplier’s documentation demonstrating that the attendance and weight loss, if applicable, performance goal(s) for the performance payment were achieved. We note that as we finalized at §424.59(b) in the CY 2017 PFS final rule (proposed to be redesignated and amended at §424.205(g)), MDPP suppliers are required to maintain and handle any personally identifiable information (PII) and protected health information (PHI) in compliance with HIPAA, other applicable state and federal privacy laws, and CMS standards. Therefore, MDPP suppliers must follow these rules when providing any copies of information from a beneficiary’s MDPP records to another MDPP supplier.
We are proposing that any weight loss measurement taken and recorded by an MDPP supplier for the purposes of performance payments must be taken in person during an MDPP core session, core maintenance session, or ongoing maintenance session by the MDPP supplier during the MDPP services period. We believe that in-person measurements are the most feasible method for weight ascertainment at this time for services because the beneficiary would attend regular in-person sessions with the MDPP supplier. Moreover, we believe that self-reported weight loss is not reliable for the purposes of performance payment in the MDPP expanded model. This proposal also would apply to our proposed policy regarding virtual make-up sessions, described in detail in section III.K.2.c.iv.(3) of this proposed rule, meaning that weight loss could not be measured or reported during a virtual make-up session for the purpose of the MDPP supplier submitting a claim for a performance payment. We also are proposing to require that weight loss be measured in person at an MDPP session to align with CDC’s DPRP standards, which require for in-person sessions that weight be measured in person at the session.

In addition, we note that the achievement or maintenance of the required minimum weight loss that determines the performance payment amount for a core maintenance session interval and the maintenance of the required minimum weight loss that determines whether a performance payment for an ongoing maintenance session interval is made must be determined by an in-person weight measurement at a session furnished during the applicable interval. Thus, for these interval performance payments, achievement of the performance goal for minimum weight loss does not need to be determined based on attendance at a session furnished by the MDPP supplier billing for that performance payment. However, as discussed previously, if achievement of the performance goal for minimum weight loss was measured at a session furnished by a previous MDPP supplier in the interval, the subsequent supplier must have
documentation through a copy of the beneficiary’s MDPP record from that previous supplier that
the weight loss performance goal was met in the interval to bill for the interval performance
payment. Finally, the performance payments for the required minimum and 9 percent weight
loss would only be billed by the MDPP supplier furnishing the session at which the weight loss
performance goal is met during an in-person session.

Furthermore, we are proposing that the beneficiary must achieve the applicable
attendance performance goal for core session, core maintenance session interval, or ongoing
maintenance session interval performance payments upon attendance at a session furnished by
the MDPP supplier billing for that specific performance payment. An MDPP supplier can only
bill for a performance payment on the date the beneficiary has achieved all performance goals
associated with that performance payment. We note that in order to bill for an interval
performance payment that is based on attendance, the MDPP supplier that furnished the session
where the attendance goal is met would bill for the performance payment, even if that supplier
did not itself furnish all sessions attended by the MDPP beneficiary during that interval. In these
circumstances, as discussed previously, if attendance at a session furnished by a previous MDPP
supplier occurred in the interval, the subsequent supplier must have documentation through a
copy of the beneficiary’s MDPP record from that previous supplier of the session attendance in
order to bill for the interval performance payment based on attendance at that session. An
MDPP supplier may not bill for an interval performance payment when the MDPP supplier does
not furnish the session where the attendance goal is met.

For all interval performance payments, we are proposing that the performance payment
would be based on the date the MDPP supplier furnished the session where the interval
attendance performance goal is met. Thus, for those intervals where the performance payment is
based on MDPP beneficiary session attendance that spans two calendar years, the interval performance payment would be the amount applicable to the later calendar year, reflecting the annual update from the prior year as discussed in section III.K.2.d.iii.(9) of this proposed rule.

The proposed conditions for payment by CMS of performance payments and bridge payments to MDPP suppliers are included at proposed §414.84(b) and (c), as well as at the other provisions in these sections. We are inviting public comments on these proposals.

(c) Reporting HCPCS G-Codes on Claims for MDPP Services

We are proposing to establish 19 unique Healthcare Common Procedure Coding System (HCPCS) G-codes so that MDPP suppliers may submit claims for payment when all the requirements for billing the codes have been met. Our proposal for the HCPCS G-codes is displayed in Table 33.

We note that each MDPP supplier would be able to bill one of the 18 payable HCPCS G-codes on the date when all the requirements for billing the code have been met, including the session attendance for specific core and ongoing maintenance session intervals and achievement and/or maintenance of weight loss, as applicable to the specific HCPCS G-code. One of the proposed HCPCS G-codes would be nonpayable and assigned a payment amount of $0 because it would only be reported on a claim that also includes a payable HCPCS G-code for MDPP services as described subsequently in this section.

HCPCS G-codes GXXX1 through GXXX3 and GXXX8 through GXX17 may each be paid only once in a beneficiary’s lifetime, and the Medicare claims processing system would ensure that no more than one of each specific performance payment per beneficiary reported with these HCPCS G-codes is made. In addition, because only one performance payment may be made for each core maintenance session interval per beneficiary, the claims processing system
would also ensure that no more than one unit of HCPCS code GXXX4 or GXXX6 and no more than one unit of HCPCS code GXXX5 or GXXX7 was paid in a beneficiary’s lifetime.

Due to these lifetime limitations on payment for certain HCPCS codes for each beneficiary, in the circumstances where two MDPP suppliers furnished sessions during the MDPP services period and both MDPP suppliers met all requirements for billing the same HCPCS G-code, based on our operational processes, we would pay the first valid claim received and deny the second claim. The first valid claim received for a beneficiary for a given HCPCS G-code with a lifetime limitation would be determined through the CMS’ Common Working File (CWF), which processes claims for all MACs.

Based on information from the CDC’s national DPP, we expect that circumstances where a beneficiary changes MDPP suppliers during the MDPP services period will be uncommon. In addition, in view of the typical structure of DPPs where core sessions are offered weekly for the first 6 months of the core services period, and then offered monthly, we believe it would be rare for more than one MDPP supplier to meet the requirements for billing for the same once-per-lifetime performance payment. However, as an example an MDPP beneficiary could maintain the required minimum weight loss throughout the first core maintenance session interval and attend 3 sessions furnished by one MDPP supplier in the first 1 ½ months of the first core maintenance interval, and then change to another supplier and attend 3 more core maintenance sessions furnished by a subsequent MDPP supplier before the end of that interval. While both MDPP suppliers would meet the requirements for billing HCPCS code GXXX6, we would only pay the first claim for the HCPCS G-code that was submitted. The second claim for HCPCS code GXXX6 received by us would be denied. We expect that our operational processes will result in MDPP suppliers submitting claims for HCPCS G-codes as soon as the sessions are
furnished that meet all of the requirements for billing for the particular performance payment, and that this practice will generally result in the performance payment being made to the MDPP supplier that furnished the first session where the performance goals were met.

Finally, as discussed in section III.K.2.d.v. of this proposed rule, we are not proposing to limit the number of bridge payments, which would be reported with HCPCS code GXX18, that may be paid for an MDPP beneficiary who changes MDPP suppliers during the MDPP services period.
**TABLE 33: Proposed HCPCS G-Codes for MDPP Services**

<table>
<thead>
<tr>
<th>Proposed HCPCS G-Code for MDPP Services*</th>
<th>Proposed Payment Amount</th>
<th>Description of MDPP Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>GXXX1</td>
<td>$25</td>
<td>1st core session attended</td>
</tr>
<tr>
<td>GXXX2</td>
<td>$30</td>
<td>4 total core sessions attended</td>
</tr>
<tr>
<td>GXXX3</td>
<td>$50</td>
<td>9 total core sessions attended</td>
</tr>
<tr>
<td>GXXX4</td>
<td>$10</td>
<td>3 core maintenance sessions attended in months 7-9 (weight loss goal not achieved or maintained)</td>
</tr>
<tr>
<td>GXXX5</td>
<td>$10</td>
<td>3 core maintenance sessions attended in months 10-12 (weight loss goal not achieved or maintained)</td>
</tr>
<tr>
<td>GXXX6</td>
<td>$60</td>
<td>3 core maintenance sessions attended in months 7-9 and weight loss goal achieved or maintained</td>
</tr>
<tr>
<td>GXXX7</td>
<td>$60</td>
<td>3 core maintenance sessions attended in months 10-12 and weight loss goal achieved or maintained</td>
</tr>
<tr>
<td>GXXX8</td>
<td>$160</td>
<td>5 percent weight loss from baseline achieved</td>
</tr>
<tr>
<td>GXXX9</td>
<td>$25</td>
<td>9 percent weight loss from baseline achieved</td>
</tr>
<tr>
<td>GXX10</td>
<td>$50</td>
<td>3 ongoing maintenance sessions attended in months 13-15 and weight loss goal maintained</td>
</tr>
<tr>
<td>GXX11</td>
<td>$50</td>
<td>3 ongoing maintenance sessions attended in months 16-18 and weight loss goal maintained</td>
</tr>
<tr>
<td>GXX12</td>
<td>$50</td>
<td>3 ongoing maintenance sessions attended in months 19-21 and weight loss goal maintained</td>
</tr>
<tr>
<td>GXX13</td>
<td>$50</td>
<td>3 ongoing maintenance sessions attended in months 22-24 and weight loss goal maintained</td>
</tr>
<tr>
<td>GXX14</td>
<td>$50</td>
<td>3 ongoing maintenance sessions attended in months 25-27 and weight loss goal maintained</td>
</tr>
<tr>
<td>GXX15</td>
<td>$50</td>
<td>3 ongoing maintenance sessions attended in months 28-30 and weight loss goal maintained</td>
</tr>
<tr>
<td>GXX16</td>
<td>$50</td>
<td>3 ongoing maintenance sessions attended in months 31-33 and weight loss goal maintained</td>
</tr>
<tr>
<td>GXX17</td>
<td>$50</td>
<td>3 ongoing maintenance sessions attended in months 34-36 and weight loss goal maintained</td>
</tr>
<tr>
<td>GXX18</td>
<td>$25</td>
<td>Bridge payment – first session furnished by MDPP supplier to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier</td>
</tr>
<tr>
<td>GXX19</td>
<td>$0</td>
<td>MDPP session reported as a line-item on a claim for a payable MDPP services HCPCS G-code for a session furnished by the billing supplier that counts toward achievement of the attendance performance goal for the payable MDPP services HCPCS G-code</td>
</tr>
</tbody>
</table>

* = Illustrative HCPCS G-code numbers are placeholders to allow for comment on this proposed rule. Final HCPCS codes for MDPP services under the MDPP expanded model will be included in the CY 2018 PFS final rule.
We also plan to issue specific billing instructions to MDPP suppliers for those 14 proposed HCPCS G-codes (excluding GXXX1, GXXX8, GXXX9, GXX18, and GXX19) that represent an interval performance payment where attendance at more than 1 session is required for the performance payment to be made. Suppliers would report the applicable HCPCS G-code as a line-item on the claim on the date the session was furnished where the interval attendance goal was met. On the same claim, suppliers would also report 1 line-item of HCPCS code GXXX19 for each other session furnished by the supplier during the interval that was not previously reported on a claim but that counts toward achievement of the attendance performance goal for the applicable HCPCS G-code.

For example, while beneficiary attendance at the 2\textsuperscript{nd} and 3\textsuperscript{rd} of the 4 core sessions would not result in a separate performance payment, we would instruct MDPP suppliers that the 2\textsuperscript{nd} and 3\textsuperscript{rd} core sessions furnished by the supplier submitting the claim for HCPCS code GXXX2 (4 total core sessions attended) be reported as 2 separate line-items of HCPCS code GXX19 on the claim for the performance payment for 4 core sessions attended. The 4\textsuperscript{th} core session furnished by the billing supplier where the interval attendance goal was met would be represented on the claim line reporting HCPCS code GXXX2. Each of these line-items (one line-item of GXXX2 and 2 line-items of GXX19) would include the date of service and the NPI of the coach associated with that MDPP supplier who furnished the specific session reported as the line-item.

When billing for a HCPCS G-code that represents a cumulative number of MDPP sessions where some sessions already have been reported on a previous claim, only the sessions not previously reported on a claim would be reported by the MDPP supplier. For example, HCPCS code GXXX3 (9 total core sessions attended) would be used to bill for 9 core sessions attended, and the line-item of HCPCS code GXXX3 would represent the 9\textsuperscript{th} core session.
furnished. Separate line-items of HCPCS code GXX19 would be reported on the same claim only for the 5th through 8th core sessions furnished by the MDPP supplier. Claims for HCPCS codes GXXX1 (1st core session attended) and GXXX2 (4 core sessions attended) would already have been submitted, and those claims would have included line-items for the 1st core session, and for the 2nd, 3rd, and 4th core sessions.

We believe that instructing MDPP suppliers to report a line-item for each session on a single claim submitted for an interval performance payment would simplify the tracking and administrative activities of MDPP suppliers and the reporting of the coach NPI on claims for MDPP services furnished to beneficiaries as discussed in section III.K.2.d.iii.(10)(d) of this proposed rule. We further believe that there should be no significant administrative burden for MDPP suppliers to include information on all sessions they furnished on interval performance payment claims for two reasons. First, the documentation requirements for MDPP sessions at §424.205(g), including the beneficiary’s eligibility, specific session topics attended, the NPI of the coach who furnished the session attended, the date and place of service of sessions attended, and weight, would require the MDPP supplier to document and retain this information. Therefore, MDPP suppliers would have documentation of the date of each session and the NPI of the furnishing coach for reporting on each line-item on the claim for the interval performance payment. Second, MDPP suppliers would be instructed not to submit separate claims for each session represented in an interval performance payment. All sessions would be reported on the single claim that would be submitted for the interval performance payment.

In the case of an MDPP supplier submitting a claim for an interval performance payment where the billing supplier did not furnish all the sessions attributable to the interval because another supplier had furnished some of the first sessions in the interval, the billing supplier
would report on the claim only the sessions it furnished. However, the supplier would need to maintain MDPP records documenting that all requirements, including session attendance and achievement or maintenance of weight loss, if applicable, for billing the HCPCS G-code for the interval for the beneficiary were met. Any sessions covered by the interval performance payment HCPCS G-code but not furnished by the supplier submitting the claim for that interval would not be reported as separate line-items on the claim. However, the billing supplier would need to maintain in the beneficiary’s MDPP record a copy of his or her MDPP record from the previous supplier in order to consider sessions furnished by the previous supplier in determining that the performance goal(s) for the interval performance payment were met.

Although the NPIs of the coaches who furnished such sessions that would not be reported as separate line-items would also not be recorded on the claim, the billing supplier would still be required to maintain documentation in the beneficiary’s MDPP record of the NPI of each coach who furnished each session through a copy of the beneficiary’s MDPP record about those sessions from the previous supplier. Therefore, upon medical review, CMS and its contractors would be able to review and assess the remaining coaches who furnished sessions to Medicare beneficiaries associated with a claim submitted for a given interval performance payment HCPCS G-code, but who do not have an NPI reported on the claim. Because we expect it to be uncommon for suppliers not to furnish all sessions attributable to an interval and due to the administrative burden that could result from a requirement that an MDPP supplier report specific information on sessions on a claim that the particular supplier did not itself furnish, we believe the program integrity risk associated with the limitation in the completeness of information from administrative claims data under this scenario is low. However, we will monitor the completeness of reporting line-items on claims for interval performance payments and may
consider revising our billing instructions in the future if we determine that we lack information from administrative claims on a significant number of sessions furnished to MDPP beneficiaries.

We are inviting public comments on the proposal to create 19 HCPCS G-codes for billing for the performance payments and bridge payment and reporting additional session line-items on claims for MDPP services. We also are inviting public comment on matters related to billing instructions for MDPP suppliers that we plan to issue so that information on the date and furnishing coach NPI for all sessions furnished by the billing supplier would be submitted on claims. However, we note that we intend to provide additional claims submission instructions in guidance.

(d) Reporting the Coach National Provider Identifier (NPI) on Claims

In the CY 2017 PFS final rule, we established the policy that coaches will not enroll in Medicare for purposes of furnishing MDPP services, but that they will be required to obtain NPIs. Further details on these policies are described in section III.K.2.e.iii. of this proposed rule.

According to Chapter 26, Section 10.4 of the Medicare Claims Processing Manual, the NPI of the rendering provider is to be reported as Item 24J on the line-item for each service reported on the CMS-1500 claim form. Our proposal in section III.K.2.d.iii.(10)(c) of this proposed rule would require that, in the circumstances of a claim for an interval performance payment for MDPP services, each session furnished by the billing supplier be reported as a separate line-item on the claim. In addition, we are proposing to require MDPP suppliers to report the NPI of the coach who furnished the session as Item 24J on the line-item for each session reported on claims for performance payments for MDPP services. Under our proposal,

the coach who furnished the session would be the rendering provider for purposes of reporting on the CMS-1500 claim form.

While only MDPP suppliers, not coaches, would be subject to potential Medicare administrative actions related to payments the suppliers may receive, we believe that our proposal to require the NPI of the coach who furnished the session to be reported as the rendering provider for each line-item HCPCS G-code on a claim for MDPP services would provide us with a number of program integrity protections, including the ability to monitor MDPP coach activity to identify suspected fraud or other improper payments and to determine the need for medical review or investigation as appropriate. We would only process claims for payment of MDPP services when all of the coach NPIs reported on the claim are associated with eligible coaches who have been submitted on the coach roster in the MDPP supplier’s enrollment application, and when all of the coaches have successfully completed Medicare’s screening processes. We would also only process claims for payment of MDPP services furnished by a coach on or after his or her coach eligibility start date, and, if applicable, prior to his or her coach eligibility end date, as the definitions of these terms are included in proposed §424.205(a).

Without such program integrity protections, we would lack a sufficient method to verify that payment is being made for services furnished by a coach who has met the requirements outlined in section III.K.2.e.iii. of this proposed rule. This verification will help protect both Medicare beneficiaries and the Medicare Trust Funds. Including coach NPIs on claims may also encourage accuracy in reporting on the achievement of beneficiary attendance and/or weight loss performance goals because both CMS and MDPP suppliers would be able to identify on the claim in question which coaches furnished the sessions attributable to the performance payment. In addition, because the accuracy of information reported on the claim is ultimately the MDPP
supplier’s responsibility, and the MDPP supplier attests to the accuracy of each claim submitted, including the relevant coach NPIs on the claim may assist the MDPP supplier when conducting internal monitoring of claim accuracy.

These proposed requirements for reporting the coach NPI as the rendering provider on session line-items included on claims for performance payments and bridge payments to MDPP suppliers are included at proposed §414.84(b) and (c). We are inviting public comments on these proposals.

iv. Comparison of Supplier Requirements for Furnishing the Set of MDPP Services and Supplier Payment

As in the DPP model test under section 1115A(b) of the Act, MDPP services are based on a CDC-approved DPP curriculum and, therefore, MDPP suppliers must offer sessions in accordance with that curriculum. We are proposing to apply a performance-based payment methodology to MDPP services, which ties most payments to outcomes – in this case, weight loss and session attendance - to help incentivize suppliers to be engaged in their beneficiaries’ weight loss efforts. Given this proposed methodology, we recognize that there would be an inherent amount of supplier financial risk, and that coverage of sessions and supplier requirements and payment would not always align. This section aims to clarify how we are proposing that these elements would fit together in the MDPP expanded model, as displayed in Table 34.
### TABLE 34: Set of MDPP Services and Payment

<table>
<thead>
<tr>
<th>MDPP Services</th>
<th>MDPP Beneficiary Eligibility for Coverage</th>
<th>MDPP Supplier Must Offer</th>
<th>MDPP Supplier Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core sessions (months 1 to 6 of the MDPP services period)</td>
<td>An eligible beneficiary has Medicare coverage of core sessions in the first 6 months of the MDPP core services period, regardless of attendance or weight loss. *NOTE: To start the MDPP services period, the beneficiary attends his or her first core session, which begins the beneficiary’s MDPP services period timeline of a maximum of 36 months.</td>
<td>At least 16 core sessions, furnished no more frequently than once per week, over the first 6 months of the beneficiary’s MDPP services period.</td>
<td>• $25 performance payment for beneficiary attendance at the first core session. &lt;br&gt; • $30 interval performance payment after the beneficiary has attended a total of 4 core sessions. &lt;br&gt; • $50 interval performance payment after the beneficiary has attended a total of 9 core sessions. &lt;br&gt; *NOTE: All payments for core sessions are independent of beneficiary weight loss.</td>
</tr>
<tr>
<td>Core maintenance sessions (months 7 to 12 of the MDPP services period)</td>
<td>Beneficiary has coverage of core maintenance sessions in months 7 to 12 of the MDPP services period, regardless of attendance or weight loss.</td>
<td>At least 1 core maintenance session per month in months 7 to 12 of the MDPP services period.</td>
<td>• $10 payment if a beneficiary attends 3 sessions within a 3-month core maintenance session interval but does not achieve or maintain the required minimum weight loss at least once within that 3-month core maintenance session interval; or &lt;br&gt; • $60 if a beneficiary attends 3 sessions and achieves or maintains the required minimum weight loss at least once within that 3-month core maintenance session interval. &lt;br&gt; *NOTE: There are two consecutive core maintenance session intervals.</td>
</tr>
<tr>
<td>Ongoing maintenance sessions (months 13 to 36 of the MDPP services period)</td>
<td>Beneficiary has coverage of ongoing maintenance sessions in the first ongoing maintenance session interval (months 13 to 15 of the MDPP services period) if:  &lt;br&gt; • He or she attended at least 1 session during the final core maintenance session interval (months 9 to 12)</td>
<td>At least 1 ongoing maintenance session per month for up to 24 months, if the beneficiary maintains eligibility to have coverage</td>
<td>• $50 payment if a beneficiary attends 3 sessions and maintains the required minimum weight loss from baseline at least once within a 3-month ongoing maintenance session interval. &lt;br&gt; *NOTE: There are up to eight consecutive ongoing maintenance session intervals.</td>
</tr>
<tr>
<td>MDPP Services</td>
<td>MDPP Beneficiary Eligibility for Coverage</td>
<td>MDPP Supplier Must Offer</td>
<td>MDPP Supplier Payment</td>
</tr>
<tr>
<td>---------------</td>
<td>------------------------------------------</td>
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</tr>
</tbody>
</table>
|               | of the MDPP services period) and had weight measured.  
• He or she achieved or maintained the required minimum weight loss at least once during the final core maintenance session interval (months 10 to 12 of the MDPP services period).  
A beneficiary has coverage of a subsequent ongoing maintenance session interval (for up to 21 months after the end of the first ongoing maintenance session interval), if he or she attended at least 3 sessions and maintained the required minimum weight loss from baseline at least once during the previous ongoing maintenance session interval. | of ongoing maintenance sessions. | 

Once an MDPP supplier enrolls in Medicare to furnish MDPP services, it must offer the set of MDPP services in accordance with the MDPP supplier standards (noted in section III.K.2.e.iv.(4) of this proposed rule and at §424.205(d), including that it must offer at least 16 core sessions, furnished no more frequently than once per week, over the first 6 months of the MDPP core services period; at least 1 core maintenance session per month over months 7 to 12 of the MDPP core services period; and at least 1 ongoing maintenance session per month for up to 24 additional months (months 13 through 36 of the MDPP services period), if the beneficiary maintains eligibility for coverage of ongoing maintenance sessions. We recognize that
beneficiaries might not attend these sessions. However, they must be made available, in accordance with CDC’s DPRP standards, to beneficiaries as long as they are eligible for coverage of MDPP sessions. We further note that the set of MDPP services must be furnished in compliance with all applicable federal laws and regulations.

Although a beneficiary is not required to use MDPP services at all, the MDPP services period is initiated by the beneficiary attending his or her first core session, which begins the MDPP services period timeline. To qualify for coverage of ongoing maintenance sessions, a beneficiary would also need to attend at least 1 session during the final core maintenance session interval where in-person weight measurement is performed that demonstrates the achievement or maintenance of the required minimum weight loss.

All of the proposed performance payments except for the weight loss performance payments require the achievement of an attendance performance goal, and if a beneficiary does not achieve attendance performance goals, an MDPP supplier would not be paid a performance payment that relies on achieving those goals. For example, if a beneficiary does not attend 3 sessions in the first core maintenance session interval, a supplier would not be paid a performance payment for the interval that spans months 7 to 9 of the MDPP core services period. However, a supplier must offer at least 1 core maintenance session per month to the beneficiary to ensure that the beneficiary has the opportunity to attend. Furthermore, while the proposed weight loss performance payments are based solely on the achievement of the required minimum or 9 percent weight loss, we note that all weight loss measurements must be obtained in person at a session so that if a beneficiary does not attend a session where weight loss can be measured and compared to baseline, the MDPP supplier would not be paid a performance payment that relies on achieving a weight loss performance goal.
v. Payment Policies When a Beneficiary Changes MDPP Suppliers

In the CY 2017 PFS final rule (81 FR 80470), we confirmed that a beneficiary may change MDPP suppliers at any time. However, we deferred specific policies regarding attribution of beneficiaries who change MDPP suppliers as related to payment to future rulemaking. We are making proposals for payment policies when a beneficiary changes MDPP suppliers during the MDPP services period in this section.

At proposed §414.84(a)(1), we are proposing to define “bridge payment” as a one-time payment to an MDPP supplier for furnishing its first MDPP services session to an MDPP beneficiary who has previously received one or more MDPP services from a different MDPP supplier. We use this definition in the proposed MDPP payment policies for the circumstances when a beneficiary changes MDPP suppliers for any reason during the MDPP services period after the beneficiary has attended at least the first core session.

In cases where the beneficiary changes MDPP suppliers, there is a shift in accountability for offering the set of MDPP services for which the beneficiary is eligible for coverage from one MDPP supplier to a subsequent MDPP supplier. Similar to our proposal for a performance payment to an MDPP supplier that furnishes the first core session to an MDPP beneficiary who initiates the MDPP services period as discussed in section III.K.2.d.(3) of this proposed rule, we are proposing that an MDPP supplier would be paid a bridge payment of $25 for furnishing its first session to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier, regardless of whether the MDPP supplier is paid any performance payments for that beneficiary. A subsequent MDPP supplier would be paid this bridge payment after furnishing the first session to a beneficiary and billing the appropriate HCPCS G-code only if the supplier did not furnish the first core session to the MDPP beneficiary.
We believe that making a bridge payment that is the same amount as the proposed performance payment for the first core session discussed in section III.K.2.d.iii.(3) of this proposed rule is appropriate because we expect the MDPP supplier’s resources used to be similar under both of these circumstances. The subsequent supplier would expend resources for furnishing a first session to a beneficiary, including collecting administrative information on the beneficiary who is not already known to the supplier, regardless of whether the beneficiary goes on to receive further MDPP sessions from that supplier.

We are proposing that the bridge payment would be paid to the subsequent MDPP supplier any time a beneficiary changes suppliers during the MDPP services period, regardless of when during the core services period or ongoing services period the beneficiary changes MDPP suppliers. The bridge payment is not intended to be a performance payment, which could be paid to the subsequent MDPP supplier in addition to the bridge payment if a beneficiary achieves a performance goal while receiving MDPP services from that the subsequent supplier. Rather, the bridge payment accounts for the financial risk a subsequent MDPP supplier takes on by furnishing services to a beneficiary changing MDPP suppliers during the MDPP services period. We believe that when suppliers furnish MDPP services to MDPP beneficiaries in these circumstances, they generally do not have the same opportunity for performance payments that they would have if the beneficiary had been receiving MDPP services from the supplier from the beginning of the MDPP services period because certain performance goals, such as the required minimum weight loss, might already have been achieved by the beneficiary. The proposed bridge payment policy would play an important role in ensuring access to MDPP services and freedom of choice of MDPP suppliers for those beneficiaries who either choose to or must change suppliers during the MDPP services period.
If we were to only make performance payments for MDPP services as proposed in sections III.K.2.d.iii.(3) through (6) of this proposed rule and not make a bridge payment to a subsequent supplier when an MDPP beneficiary changes suppliers during the MDPP services period, access problems could result due to the number of scenarios where subsequent MDPP suppliers offering and furnishing MDPP services would be paid no performance payment for the sessions furnished. The following examples illustrate such scenarios.

- A beneficiary changes from MDPP supplier A to MDPP supplier B after attending core session 4; attends core sessions 5 to 8 with supplier B; and then decides not to attend any more MDPP sessions. Supplier B does not meet the requirements for billing for the performance payment for the 9th core session because only 8 core sessions were attended, despite supplier B offering and furnishing core sessions 5 to 8.

- A beneficiary who has not met the required minimum weight loss performance goal changes from MDPP supplier A to MDPP supplier B after completing the first 3-month core maintenance session interval; attends 2 core maintenance sessions in months 9-12 with supplier B; and then fails to attend the 3rd core maintenance session in this interval. Supplier B does not meet the requirements for billing for the performance payment for the second core maintenance session interval despite offering and furnishing core maintenance sessions and the beneficiary eligibility for coverage of MDPP services then ends after month 12, the end of the core services period.

We believe that circumstances like these examples where subsequent MDPP suppliers would receive no payment for sessions furnished to MDPP beneficiaries who change suppliers during the MDPP services period in the absence of the bridge payment policy could lead to those MDPP suppliers preferentially seeking to furnish the remaining MDPP services during the
MDPP services period to beneficiaries who have either already achieved the required minimum weight loss, or whom they believe will attend sessions and achieve weight loss, because the required minimum weight loss is tied to eligibility for ongoing maintenance sessions and higher performance payment for core maintenance session intervals.

We note that we are proposing in section III.K.2.e.iv.(4) of this proposed rule that MDPP suppliers may not deny access to MDPP services to eligible beneficiaries based on any reason other than the supplier’s own capacity limits to furnish MDPP services to additional beneficiaries and on a discretionary basis if a beneficiary significantly disrupts the session for other participants or becomes abusive. However, MDPP suppliers could comply with this access requirement, while still preferentially seeking to furnish the remaining MDPP services in the MDPP services period to MDPP beneficiaries they believe are most likely to achieve the performance goals. To ensure beneficiary freedom of choice of MDPP supplier, including the choice to change suppliers, we believe the proposal to make a bridge payment helps mitigate the likelihood of MDPP suppliers acting on such preferences. The subsequent supplier would be paid a bridge payment for a beneficiary who changes suppliers, even if the beneficiary does not achieve performance goals that result in a performance payment being made to the subsequent supplier.

We considered an alternative policy in which the bridge payment would only be made in circumstances where the subsequent supplier would not be paid a performance payment that is based on attendance at the first session furnished by that supplier. For example, under this alternative if a beneficiary attends the 1st session during the ongoing maintenance session interval for months 13 through 15 at one MDPP supplier and then changes to a subsequent MDPP supplier that furnishes two additional ongoing maintenance sessions within that same
interval and the beneficiary maintains the required minimum weight loss, the subsequent supplier would not be paid the $25 bridge payment but would be paid the ongoing maintenance session interval performance payment for months 13 through 15. The subsequent supplier would only be paid the $25 bridge payment if the beneficiary did not maintain the required minimum weight loss for the performance payment for that ongoing maintenance session interval. We are not proposing this alternative because we believe it is appropriate to make a bridge payment for the first session furnished by the subsequent supplier that expends resources for furnishing a session to a beneficiary not previously known to that supplier, unrelated to whether or not the beneficiary achieves a performance goal that results in a performance payment being paid to the subsequent supplier.

We are proposing that an MDPP supplier can be paid either one performance payment for furnishing the first core session or one bridge payment per beneficiary, but not both. We are proposing this policy because we believe that the potential to be paid both a performance payment for the first core session and a bridge payment, or multiple bridge payments, for the same beneficiary, could increase the risk of MDPP suppliers encouraging discontinuous care patterns. Such patterns could hinder the achievement of the required minimum weight loss that leads to a reduction in the incidence of type 2 diabetes and could lead to increased Medicare expenditures for MDPP services. Financial incentives resulting from the potential for multiple bridge payments to a single supplier for one beneficiary could lead MDPP suppliers to encourage beneficiaries to repeatedly change among them between sessions during the MDPP services period so that the suppliers may repeatedly bill for bridge payments. We believe that limiting the bridge payment to one per beneficiary per supplier and making it available for payment only if the performance payment for the first core session was not paid to that same supplier helps
mitigate this risk. However, we are not proposing to limit the number of MDPP suppliers that may be paid a bridge payment for a particular beneficiary because we are not proposing to limit beneficiary freedom of choice for MDPP suppliers. We are proposing only to limit the bridge payments that a particular MDPP supplier may be paid for each MDPP beneficiary to one.

While this proposed limit is intended to provide some protection against MDPP suppliers encouraging certain care patterns for the purposes of their financial gain alone, we understand there may be organizations enrolled in Medicare as the same supplier type but under separate MDPP supplier enrollment records that are part of a larger franchise or umbrella organization with shared financial interests. There is some program integrity risk that these organizations could coordinate to bill multiple bridge payments that would ultimately increase total MDPP payments to separately enrolled MDPP suppliers to serve the financial interests of the umbrella organization. This scenario could occur if MDPP suppliers systematically encourage beneficiaries to change suppliers for the purpose of being paid the bridge payment.

Although we believe that organizations under a larger umbrella organization may have a greater financial incentive and opportunity to engage in this behavior, we understand that any two or more MDPP suppliers could coordinate in this way, potentially affecting large numbers of MDPP beneficiaries. To mitigate this risk, we are proposing to prohibit MDPP suppliers and other individuals or entities performing functions or services related to MDPP services on an MDPP supplier’s behalf from unduly coercing an MDPP beneficiary’s decision to change or not to change to a different MDPP supplier, including through the use of pressure, intimidation, or bribery as described further in section III.K.2.e.iv.(4) of this proposed rule. We will monitor MDPP supplier billing patterns to detect how frequently bridge payments are paid and to determine whether patterns exists that may suggest fraudulent activity regarding bridge payment
claim submissions across suppliers, conducting audits, medical reviews, and investigations as appropriate.

In the CY 2017 PFS final rule, we finalized at §410.79(b) that a beneficiary’s baseline weight refers to the MDPP beneficiary’s body weight recorded during that beneficiary’s first core session. This definition applies to determine weight loss throughout the MDPP services period. Additionally, the once-per-lifetime policy finalized at §410.79(d)(1) applies if a beneficiary changes MDPP suppliers, and the services furnished by the subsequent supplier would begin where the beneficiary left off with the previous supplier. We recognize these policies may require the beneficiary to request that a copy of his or her MDPP record be provided by the previous supplier to the subsequent supplier so that subsequent supplier can determine whether the beneficiary achieves or maintains the required minimum weight loss and has information about the MDPP services already furnished. We also finalized at §424.59(b) (proposed to be redesignated and amended as §424.205(g)) that an MDPP supplier shall maintain documentation that includes services furnished and body weight measurements. Finally, we finalized at §424.59(b) (proposed to be redesignated and amended as §424.205(g)) that MDPP suppliers are required to maintain and handle any beneficiary PII and PHI in compliance with HIPAA, other applicable privacy laws and CMS standards. Any sharing of information from a beneficiary’s MDPP record between MDPP suppliers must follow these rules.

We are considering ways to streamline the sharing of this information between suppliers, such as through the development of a model tracker that logs the contact information of a beneficiary’s previous supplier and/or coach, and the beneficiary’s attendance and weight loss. Beneficiaries could take the tracker with them if they change suppliers during the MDPP services period. Such a tracker would not supplant the previous supplier’s beneficiary MDPP record
which the subsequent supplier would need to have a copy of in order to consider sessions furnished by the previous supplier in determining whether the subsequent supplier could bill for a performance payment that was based in part on those prior sessions as discussed in section III.K.2.d.iii.(10)(b) of this proposed rule. If the subsequent supplier does not have the beneficiary’s MDPP record from the previous supplier, the subsequent supplier cannot use information from the sessions furnished by the previous supplier, such as weight or session attendance, to determine that the performance goals for a performance payment were met so that the subsequent supplier can bill for the performance payment. However, it may help facilitate the process for subsequent suppliers to enroll beneficiaries partway through the MDPP services period while the subsequent supplier is coordinating with the previous supplier to obtain a copy of the beneficiary’s MDPP record from that supplier. We are inviting public comments on additional ways this data sharing could be streamlined between suppliers.

The proposed bridge payment is included at proposed §414.84(c). We are inviting public comments on this proposal and the alternative considered.

e. Supplier Enrollment and Compliance

In the CY 2017 PFS final rule, we established MDPP supplier enrollment eligibility and revocation policies at §424.59. We propose to add subpart I, which includes §§424.200, 424.205, and 424.210. This subpart specifies the requirements for Medicare Diabetes Prevention Program suppliers and beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model. We propose to redesignate all requirements under §424.59 to §424.205. These requirements previously finalized in the CY 2017 PFS final rule created MDPP suppliers as a new Medicare supplier type, and require that any organization seeking to furnish and receive payment for MDPP services must enroll as this supplier type. Given that the
set of MDPP services utilizes CDC’s DPRP curriculum, in the CY 2017 PFS final rule we established supplier eligibility criteria that closely match CDC’s DPRP standards. The CY 2017 PFS final rule provides that any organization that meets full CDC DPRP recognition will be eligible to enroll as an MDPP supplier. In this proposed rule, we are proposing to build on these eligibility criteria for enrollment, as well as make some changes, as described in further detail later in this section.

The CY 2017 PFS final rule also established other requirements related to MDPP suppliers. For example, we assigned MDPP suppliers to the high-risk screening category under §424.518. We also established the policy that coaches will not enroll in Medicare for purposes of furnishing MDPP services, but that they would be required to obtain NPIs. We established that MDPP suppliers must submit the active and valid NPIs of all affiliated coaches and provide updates of this information to us within 30 days of a coach beginning or ceasing to furnish MDPP services. We provided that this roster of coach information must include the first and last name, social security number (SSN), and NPI. The proposals outlined in this section seek to build on these requirements.

In the CY 2017 PFS final rule, we acknowledged that many DPP organizations have not yet achieved full CDC DPRP recognition, and that it might take 36 months to meet CDC’s performance standards for full recognition. We believe allowing only organizations with full recognition to enroll as an MDPP supplier would limit the number of organizations with demonstrated capacity to furnish MDPP services, and therefore, constrain beneficiary access to these services. However, we deferred to future rulemaking addressing the issue of allowing certain DPP organizations with less than full CDC recognition to enroll in Medicare.
We are proposing an MDPP interim preliminary recognition standard under CMS authority (proposed at §424.205(c)). We also are proposing that organizations that meet this standard would be eligible to enroll in Medicare as an MDPP supplier.

i. Preliminary Recognition

The current CDC 2015 Diabetes Prevention Recognition Program (DPRP) Standards do not have standards for preliminary recognition. In the CY 2017 PFS final rule, we indicated that we would align the CDC’s DPRP and the set of MDPP services, to the extent possible. It will not be possible for CMS to permit DPP organizations to enroll as MDPP suppliers based on achievement of any new CDC standard through this rulemaking because any updates to the CDC Standards are not expected to go into effect until 2018.

However, our intent is to allow organizations that do not yet have full recognition, but have demonstrated a capacity to furnish DPP services, to enroll in Medicare as of the effective date of the enrollment policies proposed in this rule. We believe this will increase access to MDPP services. For this reason, we are proposing, at §424.205(c), to establish an MDPP interim preliminary recognition standard to permit DPP organizations who meet this standard to enroll in Medicare even if they do not have full CDC recognition. This MDPP interim preliminary recognition standard will be hereafter referred to as “interim preliminary recognition.” As we stated in CY 2017 PFS final rule, our intent with this policy is to bridge the gap until such time as any CDC preliminary recognition standards are established. Once we have established the transition process with CDC, we would expect DPP organizations that seek to enroll into Medicare to obtain CDC preliminary recognition, but MDPP suppliers who have enrolled in Medicare with interim preliminary recognition would maintain their enrollment eligibility as an MDPP supplier.
(1) MDPP Interim Preliminary Recognition Standard

We are proposing, at §424.205(c)(2)(ii), that DPP organizations with pending CDC recognition that meet the following additional criteria would meet the interim preliminary recognition standard:

- The organization must continue to follow the current 2015 CDC DPRP Standards for data submission and submit a full 12 months of performance data to CDC on at least one completed cohort (see Appendix D, 2015 CDC DPRP Standards, https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf). For this purpose, a completed cohort is a set of at least five participants that entered into a lifestyle change program that has a fixed first and last session and runs for 12 months. An organization can have multiple cohorts running at the same time:
  - The 12-month data submission to CDC includes at least 5 participants who attended at least 3 sessions in the first 6 months, and whose time from first session attended to last session of the lifestyle change program was at least 9 months; and
  - Of the participants eligible for evaluation in the first criterion, at least 60 percent attended at least 9 sessions in months 1 through 6 and at least 60 percent attended at least 3 sessions in months 7 through 12.

All proposed data requirements reflect current reporting requirements to progress from pending recognition to full recognition through CDC’s DPRP; no new data collection would be required.

To implement the proposed interim preliminary recognition standard, DPP organizations with pending recognition would submit data following CDC’s typical recognition process. For the current standards, this includes data submission every 12 months, during the month of the
anniversary of the effective date. The organization’s data submission should include: (1) data for all sessions attended by participants from the approval date to the day before the first anniversary of the effective date, (if the organization has a 2016 effective date; this should include at least 6 months of participant data) or data for all sessions attended by participants from the last anniversary of the effective date to the day before the next anniversary of the effective date (if an organization’s effective date is before 2016); and (2) one record for each session attended by each participant during the preceding year. CDC would perform a new assessment, interim preliminary recognition, on our behalf. Our interim preliminary recognition will be evaluated by CDC based on those data submissions that use the timetables and submission deadlines that currently apply for CDC recognition. For interim preliminary recognition governed under this regulation, CDC would provide us with its recommendation as to which organizations have met the recognition standards for interim preliminary recognition, but we, using our authority, would make the final decision. CMS would not make any determination for recognition status governed under current or future CDC DPRP recognition processes. We believe that such an approach would minimize burden for DPP organizations, promote consistency in the application of the standards, and allow for a smooth transition if and when CDC adopts preliminary recognition standards. We intend to release additional guidance on the details of this process once the CDC 2018 Standards are released.

(2) MDPP Supplier Enrollment under the MDPP Interim Preliminary Recognition Standard

Our regulations at §424.59 (proposed to be redesignated and amended at §424.205 in this proposed rule) specify that a DPP organization with full CDC recognition is eligible for enrollment as an MDPP supplier if it also meets all of the other conditions for enrollment in §424.59(a) (proposed to be redesignated and amended at §424.205(b) in this proposed rule). We
are proposing that organizations that meet the MDPP interim preliminary recognition standard, as proposed in section III.K.2.e.i.(1) of this proposed rule, and meet all other enrollment conditions would also be eligible to enroll as an MDPP supplier.

We also are proposing that DPP organizations would be eligible to enroll as an MDPP supplier if they meet CDC DPRP Standards for preliminary recognition, once any such standards go into effect (proposed §424.205(c)(2)(i)). We anticipate that CDC’s preliminary recognition standards will be established on or after January 1, 2018. After the effective date of any updated CDC standards, we are proposing that MDPP suppliers who have enrolled in Medicare with MDPP interim preliminary recognition would continue to be eligible for MDPP enrollment (assuming they continue to meet all other requirements for enrollment, described in proposed §424.205(b)). We intend to ensure that any transition an MDPP supplier may make from interim preliminary recognition to CDC preliminary recognition does not disrupt its status as an MDPP supplier. We will address possible transition issues in future rulemaking or guidance, as appropriate.

We considered an alternative to wait until new CDC DPRP standards are effective to allow organizations other than those with full recognition to enroll as MDPP suppliers. However, as indicated in the CY 2017 PFS final rule, based on CDC data we believe that waiting until the new DPRP standards are effective would limit the number of organizations with demonstrated capacity to furnish the set of MDPP services from enrolling in Medicare when enrollment starts and offering MDPP services once they become effective. We are inviting public comments on this proposed MDPP interim preliminary recognition standard, including performance standards, and the use of this standard as a condition for enrollment in Medicare, and the alternative considered.

ii. Enrollment and Billing Effective Dates
(1) Date MDPP Suppliers May Begin Enrollment

As described in section III.K.2.a. of this proposed rule, we are proposing to change the start date of the MDPP expanded model to April 1, 2018. All other policies not related to the furnishing or billing of MDPP services would, if finalized, be effective January 1, 2018. Thus, although MDPP suppliers would not be able to begin furnishing MDPP services on January 1, 2018, MDPP supplier enrollment would begin on January 1, 2018, if these proposals are finalized. In the CY 2017 PFS final rule, we established that any organization wishing to furnish MDPP services must enroll as an MDPP supplier, regardless of any existing enrollment in Medicare. As indicated in section J.4. of the CY 2017 PFS final rule, we believe that including an effective date for enrollment that precedes the implementation date for MDPP services is necessary to allow organizations sufficient time to enroll as MDPP suppliers. Thus, MDPP services would only become available after there is sufficient time to enroll MDPP suppliers that will furnish those services.

(2) Effective Date of MDPP Suppliers’ Billing Privileges

Under §424.502, the definition of enroll/enrollment means “the process that Medicare uses to establish eligibility to submit claims for Medicare-covered items and services, and the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services.” Thus, the purpose of enrollment is to establish billing privileges in Medicare. In accordance with our proposal that MDPP services will be available beginning on April 1, 2018, we propose that MDPP suppliers may not have an effective date of billing privileges that precedes the date that MDPP services become available (proposed at §424.205(e)(2)). Given that it typically takes an enrollment application 45-60 days to process, if an MDPP supplier submitted its application in January, the application may be approved prior to when MDPP services
become available. For this reason, we are specifying a proposal that, under no circumstances would an MDPP supplier have an effective date for billing privileges for MDPP services prior to April 1, 2018.

We propose that for MDPP supplier enrollment applications that are submitted and subsequently approved, the effective date for billing privileges would be the date the application was submitted. However for applications submitted and subsequently approved prior to April 1, 2018, we propose that the effective date for billing privileges would be April 1, 2018. This proposal is consistent with other suppliers like physicians, non-physician practitioner organizations, ambulance suppliers, and independent diagnostic testing facilities (IDTFs). However, unlike physicians, non-physician practitioner organizations, and ambulance suppliers, MDPP suppliers would not be permitted to retrospectively bill for services rendered prior to their effective date for billing privileges. Given that MDPP suppliers do not furnish services with immediate impacts on health like the aforementioned Part B suppliers, we chose to utilize the approach of IDTFs. We have established MDPP supplier standards as a condition of enrollment, as described in section III.K.2.e.iv of this proposed rule (proposed at §424.205(d)), and MDPP suppliers are required to certify in their enrollment application that they are in compliance and will continue to remain in compliance with all MDPP supplier standards. Therefore, generally, an MDPP supplier could begin furnishing services on the date the application was submitted, with the goal of having their application subsequently approved. However, payment for those services would depend upon whether the enrollment application is subsequently approved.

We propose that for any enrollment application that is denied under §424.530(a)(1) for non-compliance, but then subsequently approved due to the submission of a corrective action plan (CAP), the effective date of enrollment would be the date of the CAP submission. This
proposal is also consistent with practices for existing suppliers, and institutes an appropriate safeguard for Medicare beneficiaries and the program at-large by prohibiting services from being furnished from suppliers who are not compliant. We acknowledge, however, that if a supplier began furnishing services the date it submitted its application, but was then denied enrollment, it would not be paid for any services it furnished prior to the date it submitted the CAP, if approved. However, as described in section III.K.2.e.iv of this proposed rule (proposed at §424.205(d)), upon submitting its enrollment application, an MDPP supplier certifies that – to its knowledge – it meets and agrees to continue to meet the following MDPP supplier standards, and all other applicable Medicare requirements. Thus, at the time the MDPP supplier applicant submits its application, it should believe that its enrollment application will be approved. Examples of actions the MDPP supplier could take to improve its certainty and increase the probability that the application will be approved may include reviewing any MDPP supplier supporting documentation to fully understand MDPP supplier enrollment requirements and accompanying CMS guidance or supplier support materials, confirming compliance with the MDPP supplier standards in this rule (including conducting background checks for those who would be screened by CMS during the enrollment process as required under §424.518(c) and proposed §424.205(d)(3)), and conducting a thorough review of the enrollment application to ensure no mistakes exist in the submitted application.

We also propose that if an MDPP supplier adds a new administrative location (defined and discussed further section III.K.2.e.iii.(2) of this section of the proposed rule) that resulted in a new enrollment record or Provider Transaction Access Number (PTAN), the effective date for billing privileges would be the date the MDPP supplier began its MDPP operations at that location. We believe that this proposal is appropriate given that it follows a similar approach for
an effective date that applies to when physician organizations, non-physician practitioner
organizations, ambulance suppliers, and Independent Diagnostic Testing Facilities (IDTFs) add a
new practice location to an existing enrollment record. Though the definition of administrative
location differs from that of practice location, it provides a similar function. We seek comments
on these proposals.

iii. Enrollment Application

(1) Enrollment Application Type Applicable to MDPP Suppliers

We are proposing to require the use of a new, CMS-approved enrollment application
specific to MDPP suppliers. We believe that the creation of a new application will be more
easily navigated by and reduce the burden on new, non-traditional suppliers because the new
enrollment application will only solicit information relevant to the MDPP supplier type. As this
new enrollment application is being created specifically for the MDPP expanded model, we have
determined that this new enrollment application is exempt from the Paperwork Reduction Act in
accordance with section 1115A(d)(3) of the Act. Further, this enrollment application would be
considered an “enrollment application” for purposes of part 424 subpart P, and therefore, all
existing regulations and administrative guidance that govern the CMS-855 enrollment
applications would apply to this new form, unless otherwise specified. We also considered an
alternative option to amend the current CMS-855B Medicare Enrollment Application for
Clinics/Group Practices and Certain Other Suppliers (CMS-855B) for MDPP supplier
enrollment, but we determined that the existing length and complexity of the CMS-855B
enrollment application and its applicability to other non-MDPP suppliers may add burdens or
unnecessary confusion to MDPP suppliers given that many sections of the current CMS-855B
enrollment application would not apply to MDPP suppliers. In addition, we would need to add
new sections to solicit information specific to MDPP suppliers, which would only further increase the length of the CMS-855B enrollment application. We invite public comments on this proposal.

(2) Information on MDPP Enrollment Application

On the new MDPP enrollment application, we intend to solicit information specific to MDPP suppliers, as well as information consistent with existing reporting requirements applicable to all suppliers who enroll through the CMS-855B enrollment application, while excluding all reporting requirements that do not apply to MDPP suppliers. As a Medicare supplier enrolling under part 424 subpart P, MDPP suppliers are required to provide complete and accurate information on the MDPP enrollment application, or be subject to enrollment denial under §424.530(a)(4) or revocation under §424.535(a)(4). This requirement would include all information solicited on the MDPP-specific enrollment application. The MDPP-specific enrollment application is under development and will be available prior to its use, if this proposal is finalized. While the application is being developed, we wish to indicate some of the information we intend to include on the MDPP enrollment application, as further described in this section.

As finalized in the CY 2017 PFS final rule, §424.59(a)(5) requires that MDPP suppliers submit the active and valid NPIs of all coaches who will furnish services on the supplier’s behalf, as well as their first name, last name, and SSN (in this proposed rule, §424.59(a)(5) is proposed to be redesignated and amended at §424.205(b)(4)). We are proposing, at §424.205(b)(4), to require that MDPP suppliers provide this identifying information of the coaches directly through the enrollment application. This information will be used to complete background checks of the coaches. To accompany the coach identifying information, we
propose to require MDPP suppliers to provide an eligibility start and end date, if applicable, for each coach on the supplier’s roster. Coach eligibility start and end dates are described at length in section III.K.2.e.iv.(2). As described in more detail in section III.K.2.e.iv., the background checks would be used to prevent MDPP suppliers from allowing coaches to furnish MDPP services when certain adverse histories may indicate potential to harm Medicare beneficiaries or undermine program integrity. We outline further details on our proposed enforcement of this provision in section III.K.2.e.iv. of this proposed rule.

To enable us to conduct background checks of coaches, we are proposing that MDPP suppliers also submit to CMS the date of birth of all coaches who will furnish MDPP services (proposed §424.205(b)(4)). Combined with other identifying information, date of birth plays a critical role in validating an individual’s identity. By collecting date of birth, we would be able to more accurately screen coaches, including accurately conducting a background check, and distinguishing them in the Provider Enrollment, Chain and Ownership System (PECOS). In addition, we want to ensure that we have the capability to most accurately identify individuals reported on the form. To mitigate potential confusion or error found when individuals have common names, we are proposing to collect coach’s middle initial (if applicable) on the enrollment application (proposed §424.205(b)(4)). We believe that this proposal will help to lessen the possibility that CMS or its contractors misattribute the background of one individual for another.

We are proposing, at §424.205(d)(4), that MDPP suppliers would identify their administrative location(s) by reporting these location(s) on their enrollment application. We are proposing, at §424.205 (a), to define administrative location as the physical location associated with the supplier’s operations, from where coaches are dispatched or based, and where MDPP
services may or may not be furnished. We are proposing that an MDPP supplier must have at least one such administrative location, and report any additional administrative locations of the supplier, if MDPP services are either furnished at these locations and/or if the location reflects from where coaches are dispatched or based. For example, if an MDPP supplier operated 2 locations, but only 1 of the 2 locations associated with the entity offered MDPP, only the location offering MDPP would be considered an administrative location. If coaches began offering MDPP in community settings (described in the subsequent paragraph and proposed to be defined at §424.205(a), but were dispatched and/or based out of the other non-administrative location, then this location would then be considered under the definition of an administrative location, and would need to be reported on the MDPP enrollment application within 90 days of the change. Given that MDPP suppliers are categorized as high risk under §424.518, these administrative locations may be subject to site visits prior to approval of an enrollment application. Collecting information on the MDPP supplier’s administrative location (regardless whether they furnish services in this location) is important because we may utilize this information to verify that the organization is operational per requirements under proposed §424.205(d)(4) and (6), discussed in detail in section III.K.2.e.iii.(3) of this proposed rule.

While we recognize that many suppliers furnish MDPP services outside of their administrative locations in community settings, we are proposing to only require enrollment of the administrative locations. In proposed §424.205(a), we define “community setting” as a location where the MDPP supplier furnishes MDPP services outside of their administrative locations. A community setting is a location open to the public, not primarily associated with the supplier. Community settings may include, for example, church basements or multipurpose rooms in recreation centers. When determining whether a location is considered an
administrative location or a community setting, MDPP suppliers should consider whether their organizational entity is the primary user of that space and whether coaches are based or dispatched from this location. If so, the location would be considered an administrative location, even if this location dually serves as a community setting. In comparison, community settings are locations not primarily associated with the supplier where many activities occur, including MDPP services.

We seek public comments on these proposals.

(3) Updating Information on MDPP Enrollment Application

We are proposing, at §424.205(d)(5), that MDPP suppliers must update their enrollment application within 30 days of any changes of ownership, changes to the coach roster, or new final adverse action history of any individual or entity required to report such information on the enrollment application. We are proposing that MDPP suppliers report all other changes to information required on the enrollment application within 90 days of the reportable event. Timely reporting and updating of information plays a critical role in our ability to protect Medicare beneficiaries and protect the integrity of the Medicare program and Trust Funds. We believe that these requirements are fair and consistent with existing reporting requirements for other Medicare suppliers.

All suppliers are required to report changes of ownership and new adverse action history within 30 days. Adding the requirement that any changes to the coach roster be reported within 30 days is consistent with IDTFs requirements at §410.33(g)(2). Although IDTFs differ from MDPP suppliers in many ways, IDTFs must report a roster of supervising physicians who serve functions on the supplier’s behalf and must also report changes to this roster within 30 days. Given this similarity with IDTFs, we modeled our approach after this process. However, we
note that while MDPP suppliers would be required to submit changes to the coach roster within 30 days, we would encourage them to submit such changes as soon as possible, due to reasoning explained further in section III.K.2.e.iv.(2) of this proposed rule.

We invite public comments on these proposals.

(4) Enrollment Application Fee

In the CY 2017 PFS final rule, we finalized that MDPP suppliers would enroll in Medicare. We solicited comments on, but did not propose or finalize, an applicable application fee associated with the MDPP supplier’s enrollment. In this proposed rule, we propose to amend the definition of “institutional provider” as defined under §424.502, to include MDPP suppliers such that, §424.514, which governs the application fee, would similarly apply to MDPP suppliers. “Institutional providers” that are initially enrolling in Medicare, revalidating their enrollment, or adding a new Medicare practice location are required to submit a fee with their enrollment application. We would like to highlight that while we are proposing to include MDPP suppliers as an institutional provider, MDPP suppliers utilize administrative locations, not practice locations, and therefore the fee would not apply when adding a new administrative location to an existing enrollment record. The application fee is adjusted annually, and additional information about how the adjustment is calculated may be found in the November 7, 2016 Federal Register notice establishing the calendar year 2017 application fee (81 FR 78159).

For calendar year 2017, the application fee is $560. Section 6401(a) of the Patient Protection and Affordable Care Act (as amended by section 10603 of the Affordable Care Act, amended section 1866(j)(2)(C) of the Act to require the Secretary to impose a fee on each institutional provider of medical or other items or services or supplier. This fee would be used for program integrity efforts including to cover the cost of screening and to carry out the provisions of
sections 1866(j) and 1128J of the Act. Given that section 10603 of the Affordable Care Act excludes individual practitioners, such as physicians and nurse practitioners, from paying an enrollment application fee, we have previously determined that an “institutional provider” to include any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and non-physician practitioner organizations), CMS–855S or associated Internet-based PECOS enrollment application\textsuperscript{26}. MDPP suppliers are entities, and not individual practitioners. We believe that they would similarly qualify as a “provider of medical or other items or services” used to define institutional providers. Taken together, we believe that the definition of institutional provider would also apply to MDPP suppliers. Given that the CY 2017 PFS final rule established that MDPP suppliers would be screened under high categorical risk (codified at §424.59(a)(3), proposed to be redesignated as §424.205(b)(3)(i)), the application fee would play an important role in executing particular aspects of the high-risk screening. As we noted in the CY 2017 PFS final rule, any organization that faces financial difficulty related to the application fee may apply for a hardship exception. For more information on the hardship exemption, see https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7350.pdf. We are soliciting comments on this proposal.

iv. MDPP Supplier Standards

We are proposing to establish standards that MDPP suppliers must meet and remain in compliance with to be eligible to receive payment for an MDPP service (proposed §424.205(d)). These supplier standards would build on the conditions for enrollment established under existing §424.59(a) (which in this proposed rule is proposed to be redesignated and amended at paragraph

\textsuperscript{26} See CMS-6028-FC for further discussion, 76 FR 5862 and 5907 through 5908 (Feb. 2, 2011).
§424.205(b)), as well as any existing Medicare requirements that apply to all suppliers. We are proposing that an MDPP supplier wishing to participate in MDPP must adhere to current Medicare MDPP supplier requirements as outlined in §424.59 (proposed to be redesignated as §424.205), as well as all other requirements that apply to Medicare providers and suppliers. MDPP suppliers may choose to utilize a third party administrator, billing agent, or other entity to comply with the requirements of §424.59 (proposed to be redesignated as §424.205). Regardless of any use of such entities, any failure to comply with the standards of §424.205(d) or other relevant Medicare requirements, may result in an enrollment denial under §424.530(a)(1), revocation of the MDPP supplier for non-compliance under §424.535(a)(1) or other revocation authority, as appropriate (as proposed in §424.205(g)). Consistent with existing regulations, we are proposing that MDPP suppliers would have appeal rights under part 498.

We believe that the standards outlined in this section are generally consistent with standards established for other Medicare suppliers while adding safeguards to help ensure compliance with MDPP rules and regulations specific to this expanded model. Because this expanded model would pay MDPP suppliers based on a beneficiary’s achievement of performance goals, we believe that it is prudent to include additional requirements consistent with the Office of the Inspector’s General’s compliance guidance, to promote adherence to applicable statutes, regulations, and program requirements and help reduce fraud, waste, and abuse. In addition to the proposed standards, the MDPP expanded model will be routinely monitored for compliance with supplier standards, consistent with section 1893 of the Act (42 U.S.C. 1395ddd). Although we recognize that these standards may be new for MDPP suppliers and would, if finalized, impose additional requirements on these organizations that they may not

27 https://oig.hhs.gov/compliance/compliance-guidance/.
otherwise face, both individually and collectively, these standards play an important role in ensuring the integrity of the Medicare program and the safety of our beneficiaries. Therefore, given the goals of these proposed standards to mitigate fraud, waste, or abuse to the Medicare program and its beneficiaries, we believe that they are appropriate for governing MDPP suppliers and do not place an undue burden on suppliers. We are inviting public comments on our proposed approach, as well as any unintended consequences or burdens that we may have not considered.

(1) Medicaid Terminations

In addition to establishing standards for MDPP suppliers with respect to their delivery of MDPP services, we also are proposing standards for MDPP suppliers’ general eligibility to furnish services to Medicare beneficiaries. These standards would establish program integrity safeguards that would protect both Medicare beneficiaries and the Medicare program. We are proposing that MDPP suppliers must not currently have their billing privileges terminated for cause from any State Medicaid program or be excluded from any State Medicaid program (proposed §424.205(d)(2)). If a supplier’s Medicaid billing privileges are currently terminated from or the supplier is excluded from any State Medicaid program, we do not believe that supplier should be able to furnish Medicare services. We believe that this proposal is warranted given that a supplier’s improper behavior in another Federal health care program may be duplicated in Medicare. We believe that this proposed requirement would mitigate the MDPP expanded model’s susceptibility to fraud, waste, and abuse. Consistent with all standards in this section, any MDPP supplier who does not meet this requirement would be subject to a Medicare enrollment denial or revocation. We believe that this proposed standard would serve to ensure continuity of safeguards across Federal health care programs, and will help preserve the integrity
of the Medicare program and protect beneficiaries by prohibiting suppliers found to be noncompliant in one Federal health care program from enrolling in and furnishing services in another.

We seek comments on this proposal.

(2) Ineligible Coaches: Individuals Prohibited from Furnishing MDPP Services to Medicare Beneficiaries

We are proposing, at §424.205(d)(3), that the MDPP supplier must report coach information on its enrollment application and the MDPP supplier must only permit MDPP services to be furnished by individual coaches who meet the eligibility criteria. We propose, at §424.205(e)(1) that MDPP coach eligibility criteria require that a coach must not:

- Currently have his or her Medicare billing privileges revoked and whose reenrollment bar has not yet expired. We believe that this proposed supplier standard would protect beneficiaries from receiving MDPP services from individuals already prohibited from furnishing other Medicare services. If an individual is precluded from maintaining enrollment in Medicare for a non-MDPP service, we believe that it is prudent that they similarly not furnish MDPP services.

- Currently have his or her Medicaid billing privileges terminated for-cause or is excluded from any State Medicaid Agency (proposed at §424.205(e)(1)(ii)). We believe that this proposed supplier standard is warranted given that an individual’s improper behavior in another Federal health care program may be duplicated in Medicare. We do not believe that we should permit MDPP suppliers to allow coaches with current for-cause terminations or exclusions in Medicaid to furnish MDPP services to Medicare beneficiaries.
• Currently be excluded from any other Federal health care program, as defined in §1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act. This includes, but is not limited to, the Office of Inspector General (OIG)’s List of Excluded Individuals and Entities (LEIE). We are proposing this supplier standard for similar reasons we are proposing not to permit coaches with revocations from Medicare or current exclusions from Medicaid to furnish MDPP services.

• Currently be debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement program or activity in accordance with the Federal Acquisition Streamlining Act implementing regulations and the Department of Health and Human Services non-procurement common rule at 45 CFR part 76. We note that this includes individuals who have an active status on the General Service Administration’s System for Award Management list. We may also utilize the Bureau of the Fiscal Service, U.S. Department of the Treasury’s Do Not Pay (DNP) List as a resource for determining which individuals fall under this category. The Improper Payments Elimination and Recovery Improvement Act (IPERIA) of 2012 established the DNP to support Federal agencies with their efforts to prevent and detect improper payments by aggregating various data sources for pre-award, pre-payment eligibility verification. Data sources included in this list include Credit Alert System, Death Master File, LEIE, Office of Foreign Assets Control (OFAC), System for Award Management (SAM) Entity Registration Records, and SAM Exclusion Records. We believe that we may utilize the DNP as a method of determining whether a coach is excluded from participating in any other federal procurement or nonprocurement programs. Although coaches will not directly be receiving payment from us for furnishing MDPP services, we do not believe that payment should be made to MDPP suppliers for services furnished by individuals
excluded from federal procurement or nonprocurement programs, particularly given that MDPP payments rely on beneficiary’s achievement of performance goals that the coaches will document. Although the MDPP supplier is ultimately responsible for attesting to all claims submitted for MDPP services, we do not believe that it would be prudent to permit MDPP suppliers to allow coaches excluded from other federal procurement programs to furnish MDPP services.

- Have, in the previous 10 years, one of the following state or federal felony convictions:
  
  ++ Crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

  ++ Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

  ++ Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in the individual being convicted, as defined under 42 CFR 1001.2, having a guilty plea or having adjudicated pretrial diversion of criminal neglect or misconduct.

  ++ Any felonies that for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion that would result in mandatory exclusion under section 1128(a) of the Act.

We propose that CMS will screen each individual identified on the roster of coaches included with the supplier’s enrollment application to verify that the individual coach does not
meet any of these conditions and that the coach can provide MDPP services on behalf of an MDPP supplier (proposed at §424.205(e)(2)). We are proposing these requirements as a means to ensure the integrity and safety of the Medicare program and the beneficiaries whom we serve.

We have selected these types of felony convictions based on the risk we believe they could pose to the Medicare program and our beneficiaries. Additionally, it is consistent with existing criteria that we use to determine felonies that are detrimental to the best interest of the program and its beneficiaries as described in §424.535(a)(3)(ii). While we selected these criteria to be consistent with how we evaluate other individuals, we also sought to create a more definite list such that MDPP suppliers would have the ability to conduct background checks on coaches prior to, as well as potentially after enrolling in Medicare, to avoid receiving an enrollment denial or revocation due to failure to meet this standard. While coaches are not directly enrolled, and therefore, not directly receiving payment, we believe that it is prudent to prohibit MDPP suppliers from utilizing individuals convicted of certain felonies to furnish services to Medicare beneficiaries. Because coaches will be directly interacting with beneficiaries, recording their attendance and weight loss, we believe that a coach’s trustworthiness is vital. Consequentially, we do not believe that such coaches should have a criminal history such as those described in §424.535(a)(3)(ii).

Coaches that meet any of these criteria would be considered ineligible to furnish MDPP services, and therefore, could not be on an MDPP supplier’s roster. Coaches whose information was submitted in an MDPP supplier’s enrollment application, screened, and determined as not meeting any of these criteria would be considered eligible coaches. Although the MDPP supplier is the entity that is enrolled in Medicare and submits claims, coaches furnish MDPP services, directly interacting with the beneficiary and documenting attendance and weight loss.
Therefore, we believe that precluding individual coaches who meet any of the ineligibility criteria from directly furnishing MDPP services to Medicare beneficiaries would both help reduce fraud, waste, and abuse that could occur in the MDPP expanded model, as well as protect beneficiaries from harm.

If after screening, CMS or its contractors determine that a coach is eligible to furnish MDPP services, the coach would be assigned an eligibility start date, similar to a supplier’s enrollment effective date. We are proposing to define coach eligibility start date as follows: the start date indicated by the MDPP supplier when submitting an eligible coach’s information on the MDPP enrollment application (proposed at 424.205(a)). On the enrollment application, the MDPP supplier will include a date indicating when the coach began furnishing MDPP services. Consistent with proposals at §424.205(d)(5), the MDPP supplier must report changes to the coach roster on its enrollment application, including any new coaches added, within 30 days of such a change. Thus, the start date associated with any new coach information must be within 30 days of the date the MDPP supplier actually reports the change on its application. If the coach has not yet begun furnishing MDPP services, the MDPP supplier should indicate the date the supplier is reporting the information. Though the date reflects either when the coach began furnishing services or when the coach could ultimately be determined as eligible to begin furnishing services, after the enrollment application was submitted, CMS must still determine whether the coach is eligible (proposed at §424.205(e)(2). If we determine the coach to be eligible, then his or her eligibility start date would be the date the MDPP supplier indicated on its enrollment application. As described in III.K.2.d.(10)(d), payment can be made for services furnished by this coach on or after his or her eligibility start date.
However, if a coach was determined to be ineligible at the onset, the coach would have its eligibility start and end date on the same date, effectively never being eligible to furnish MDPP services. If the coach later became ineligible, he or she would be assigned an eligibility end date. Consistent with proposals at 414.84, payment for MDPP services is made only if such services are furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date, to an MDPP beneficiary. This could pose a situation in which an MDPP supplier could submit an updated coach roster that includes a new coach, and allow him or her to begin furnishing services based on the belief that he or she is eligible. Should, after screening, CMS or its contractors determine that the coach is ineligible, the MDPP supplier could be revoked for non-compliance. Though the MDPP supplier would have an opportunity to submit a corrective action plan that removes the ineligible coach from their enrollment application, any claims for services furnished by the ineligible coach would be denied, and the MDPP supplier would not be paid for such services. For this reason, we encourage suppliers to report changes to the coach roster as soon as possible. If the MDPP supplier submits a claim that includes a coach NPI for a coach we have not yet determined to be an eligible coach for furnishing MDPP services as of the date of service, the claim will be rejected, and the supplier will need to refile the claim with the same information once CMS has made the eligibility determination. If at that time, CMS determined the coach to be ineligible, the claim for the service provided by the coach will be denied, as described in section III.K.2.d.iii.(10)(d).

We believe that the majority of the coach ineligibility criteria described in this section is crafted in such a way that the MDPP supplier could, with reasonable certainty, conduct an independent background check on the coach, to determine whether he or she meets the
ineligibility criteria. If the MDPP supplier has any uncertainty about whether the coach meets the ineligibility criteria, they may wish to preclude the coach from furnishing services to Medicare beneficiaries until CMS determines that the coach is eligible. This would avoid a potential situation of a coach furnishing services for which the MDPP supplier could not get paid. If the MDPP supplier believes the coach is eligible and wishes to allow the coach to furnish services prior CMS determining his or her eligibility, then the MDPP supplier would assume the risk not receiving payment for claims for services rendered by the ineligible coach.

If a coach no longer provides MDPP services for an MDPP supplier, the supplier must remove that coach from its roster and indicate the date of such event to designate an eligibility end date for that coach. If the MDPP supplier voluntarily terminates its Medicare enrollment or is revoked, CMS will automatically reflect the date of this action as the coach’s eligibility end date for that MDPP supplier. We are proposing to define coach ineligibility end date as follows, the end date indicated by the MDPP supplier in submitting a change to the supplier’s MDPP enrollment application that removed the coach’s information, or the date the supplier itself was revoked from or withdrew its Medicare enrollment as an MDPP supplier.

We are proposing that CMS or its contractors would determine whether coaches submitted on MDPP rosters satisfy the previously stated criteria by using the identifying information MDPP suppliers submit on their enrollment applications (including any changes that MDPP suppliers would be required to report). This information would be checked against internal and publicly available data sources. We are proposing that, upon identification of evidence that a coach met any ineligibility criteria, we may take administrative action to deny or revoke the MDPP supplier’s enrollment as appropriate under §§424.530(a)(1) and 424.535(a)(1) (proposed at §424.205(g)(1)(ii)). Consistent with existing enrollment denial and revocation
actions, we would notify the prospective or enrolled MDPP supplier via an enrollment denial or revocation notification and include the specific reason for the administrative action. The enrollment denial or revocation notification detailing the findings and the reasoning for the determination would follow requirements under §488.18. Consistent with similar processes at §§424.530(c) and 424.535(e), we are proposing that an MDPP supplier could respond to the enrollment denial or revocation by submitting a corrective action plan (CAP) that would include the removal of the coach from its roster within 30 days of receiving the enrollment denial or revocation notification, and therefore, come into compliance and enroll or maintain its enrollment status. If MDPP suppliers believe that the decision was made in error, they could exercise existing appeal rights under part 498.

We also are proposing that if we determine that an MDPP supplier has continued to allow an ineligible coach to furnish MDPP services after having submitted a CAP removing the coach from its roster to enroll or maintain enrollment in Medicare, we would revoke the MDPP supplier without the opportunity for additional corrective action. This authority, outlined in proposed §424.205(h)(1)(v), would allow us to revoke an MDPP supplier for knowingly using an “ineligible coach” to furnish MDPP services. “Knowingly,” in this context, means that the supplier received an enrollment denial or revocation notice based on failing to meet supplier standards at §424.205(d)(3) (related to ineligible coaches), was provided notice by CMS or contractors working on its behalf of this action including the reason(s) for the administrative action, submitted a CAP to remove the coach, but continued to allow the coach to provide MDPP services in violation of the CAP. We are proposing to define an “ineligible coach” in §424.205(a) as an individual whom CMS has screened and has determined ineligible to furnish MDPP services on behalf of an MDPP supplier based on the standard specified in §424.205(e),
and we are proposing in the same paragraph to define “eligible coach” in §424.205(a) as an individual who CMS has screened and has determined can furnish MDPP services on behalf of an MDPP supplier based on the standard specified in proposed §424.205(e).

While any individual may be eligible to become a DPP coach, provided that they meet requirements and trainings as dictated by the CDC’s DPRP Standards, an individual can only become an eligible coach for purposes of furnishing MDPP services after having their required identifying information submitted on an MDPP supplier’s enrollment application, being screened by CMS or its contractors, and as a result, being determined to be eligible to furnish MDPP services on behalf of an MDPP supplier. If CMS or its contractors deem a coach ineligible, this would apply only to the furnishing of MDPP services and would not preclude the DPP organization from continuing to allow this individual to furnish administrative services or DPP sessions to non-Medicare beneficiaries. However, serving as a coach for Medicare beneficiaries would be prohibited and would be subject the MDPP supplier to this revocation authority.

We are proposing this new revocation authority due to the novel program integrity risks that would be posed by MDPP suppliers who knowingly continue to permit ineligible coaches to furnish MDPP services to Medicare beneficiaries. We believe that this new basis for revocation is necessary because coaches are not enrolled in Medicare, even though they will undergo background checks by CMS or its contractors and must meet specified criteria. While we considered using existing revocation authorities under §424.535(a)(1) (related to noncompliance), §424.535(a)(4) (related to false or misleading information), and §424.535(a)(9) (related to failure to report), we determined that these authorities were too general for purposes of specifically addressing MDPP coaches who become ineligible to furnish MDPP services. We are proposing that this revocation authority would follow similar requirements under
§424.535(c), (g), and (h). We do not believe that §424.535(e) (related to reversal of the revocation) should apply in this case, given that the MDPP supplier already had an opportunity to remove the coach from their roster by submitting a CAP, but continued to allow the ineligible coach to furnish MDPP services. The proposals that we would apply from the provisions of §424.535 stated in this section are as follows:

- The revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the MDPP supplier;

- For the revocation authority, MDPP suppliers are barred from participating in the Medicare program from the date of the revocation until the end of the re-enrollment bar, which begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation; and

- A revoked MDPP supplier must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter.

We believe that these proposals would appropriately govern this proposed new revocation authority, given the consistency with existing revocation authorities. Given these consistencies, we do not believe that this proposal places an undue burden on MDPP suppliers, and any burden established would be warranted given the violation of the supplier standards that jeopardize both the integrity of the Medicare program and the safety of its beneficiaries.

We are inviting public comments on these proposals.

(3) Ensuring MDPP Suppliers Are Legitimate, Operational Organizations

We are proposing a number of requirements that would help ensure that MDPP suppliers are operational, have the resources necessary to furnish MDPP services, and are in compliance
with MDPP supplier standards. At §424.205(d)(4), we are proposing that, regardless of whether
the MDPP supplier furnishes services solely in community settings, it must maintain at least one
administrative location. All administrative locations maintained by the MDPP supplier must be
on an appropriate site available to the public and must be reported on the CMS-approved
enrollment application. We are proposing that this administration location may not be a private
residence. We are proposing that an appropriate site must have signage posted on the exterior of
the building, as well as be open for business and have employees, staff, or volunteers present
during operational hours. For the purposes of this requirement, such signage may include, for
example, the MDPP supplier’s legal business name or its “doing business as” (DBA) name, as
well as hours of operation. This proposal seeks to utilize measurable objective indicators to
determine that organizations are legitimately operating and able to furnish MDPP services to
Medicare beneficiaries. We believe that, regardless of whether the MDPP supplier furnishes
services at its administrative location, establishing a physical location is necessary for associated
requirements for furnishing MDPP services, including recordkeeping requirements, training
facilities, and storage for any educational materials distributed during sessions.

We are proposing, at §424.205(d)(6), that a MDPP supplier must maintain a primary
business telephone number listed under the name of the organization in public view. Public view
could signify, for example, that the phone number is listed on a website, on flyers and materials.
This proposed policy would require that calls must not automatically go to the answering
machine or utilize an answering service during posted business hours. The purpose of this
proposed requirement is to help verify that the organization is a legitimate organization and not
simply posing as an organization and seeking to bill Medicare fraudulently.
We are further proposing, at §424.205(d)(7), that an MDPP supplier must not knowingly sell to or allow another individual or entity to use its billing number, consistent with §424.535(a)(7). We are including this proposal to avoid a situation in which another entity uses an existing MDPP supplier’s billing number. We believe that this proposal plays an important role in ensuring that payments are only being made to the intended recipient who has met all of the supplier and compliance standards and that we continue to hold entities responsible for maintaining compliance. Otherwise, we risk making payments to suppliers potentially engaging in fraudulent or potentially harmful behavior.

We believe that the proposed requirements in this section would not pose an undue burden on MDPP suppliers as they are minimum requirements for any functional, operational organization. By establishing these requirements, we believe that we would ensure that MDPP suppliers that do not meet the baseline requirements for an operational organization would not be permitted to furnish MDPP services to or receive payment for such services. We are proposing, at §424.205(d)(15), that an MDPP supplier must permit CMS or its agents to conduct onsite inspections to ascertain the supplier’s compliance with these standards. While we believe that any operational business that truly furnishes MDPP services would be able to meet these requirements, we are inviting public comments on any aspects of these proposed standards.

(4) Beneficiary Access

We are proposing, at §424.205(d)(8), that MDPP suppliers may not deny access to MDPP services to eligible beneficiaries based on any reason other than the supplier’s own self-determined and published capacity limits to furnish MDPP services to additional people and, on a discretionary basis, if a beneficiary significantly disrupts the session for other participants or becomes abusive. Given that we do not yet currently have data on optimal class size for MDPP
services, we are currently allowing MDPP suppliers to self-determine any upper limitation on class size. Should they establish such a limit and intent to turn beneficiaries away once the capacity limit is reached, the MDPP supplier must have previously made this limit publicly available; for example, denoting the limit in any brochures, websites, or other materials that outline their MDPP services. We are proposing that MDPP suppliers must maintain a record of the number of eligible Medicare beneficiaries turned away for each of these reasons, as well as the date the beneficiary was informed. We are further proposing that if an MDPP supplier denies a Medicare beneficiary access citing disruptive or abusive behavior, details of the occurrence(s), including date(s) of the behavior, any remediation efforts taken by the supplier, and final action (for example, dismissal from an MDPP session or denial from future sessions) must be documented in the beneficiary’s MDPP records and adhere to documentation requirements outlined in §424.205(g). We note that one supplier’s decision to dismiss a beneficiary for this purpose would not limit that beneficiary from switching to another MDPP supplier.

We will seek to monitor compliance with this requirement, and investigate further if necessary, based on beneficiary complaints, rates of access denials citing capacity limits in comparison to estimated capacity based on claims submitted, as well as monitoring claims for success rates for achieving performance goals that are higher than what would be expected for a typical Medicare population. Illustrative examples of capacity limits could include that the MDPP supplier has met its self-determined and published class size maximum, or that the supplier is providing MDPP sessions in cohorts and does not have a new or upcoming cohort at the time the beneficiary is seeking MDPP services. Furnishing MDPP services in a cohort means that the DPP curriculum is delivered among a single group, or cohort, from start to finish with
sessions furnished in a specific order, therefore, not allowing any new individuals to join once the cohort has begun.

Given that our proposed payment structure for MDPP services relies on the achievement of weight loss and attendance goals, there may be incentives for MDPP suppliers to seek to serve only those beneficiaries for which they are more likely to earn performance payments. This, in turn, could result in discriminatory treatment of beneficiaries. Through this proposed supplier standard, we would expressly prohibit MDPP suppliers from conditioning access to MDPP services on the basis of a beneficiary’s weight or health status (except as provided in our proposed regulations). We also would prohibit MDPP suppliers from conditioning access to MDPP services on the basis of a beneficiary’s achievement of performance goals, except where the beneficiary becomes ineligible for additional sessions as a result of not meeting those goals, as proposed elsewhere in this proposed rule. We believe that it is appropriate to prohibit suppliers from denying access to MDPP services except in certain limited circumstances. If a supplier were to deny access to a beneficiary citing lack of capacity, but then furnish MDPP services to a different beneficiary, this may signal a violation of such standards. In addition, and for the same reasons, we are proposing to prohibit MDPP suppliers, which includes any coaches or entities performing functions or furnishing services related to MDPP services on their behalf, from unduly coercing a beneficiary’s decision to change or not change to a different or specific MDPP supplier, including through the use of pressure, intimidation, or bribery in proposed §424.205(d)(9). Information that may result in a beneficiary changing to a different MDPP supplier provided in response to a beneficiary’s request for information would not violate this provision.
At §424.79, the CY 2017 PFS final rule established the set of services included in the expanded model, but did not stipulate that once a supplier began furnishing such services to a beneficiary, that it must continue to offer them to the beneficiary as a part of the MDPP expanded model. We are proposing, at §424.205(d)(10), that MDPP suppliers must offer and provide beneficiary access to the entire set of MDPP services for which beneficiaries are eligible. This includes the requirement that suppliers offer at least 16 in-person core sessions, no more frequently than once per week, over the first 6 months of the core services period and offer at least 6 core maintenance sessions, at least once per month, over months 7 through 12 of the core services period (proposed at §410.79(c)(2)(i)). For beneficiaries to whom the supplier has begun furnishing MDPP services, and who meet the eligibility requirements for ongoing maintenance sessions described in proposed §410.79(c)(1)(ii) and (iii), MDPP suppliers are required to offer 24 ongoing maintenance sessions, furnished at least once per month over the course of months 13 through 36 of the MDPP services period, in 3-month consecutive increments. These requirements would also apply to any MDPP supplier who gains a beneficiary at some point during their receipt of MDPP services. Should this MDPP supplier begin furnishing services to a beneficiary at any point during the 3-year MDPP services period, it must continue to offer the services for which the beneficiary is eligible but has not yet received. For example, if a beneficiary changed suppliers after the core sessions in month 6, the subsequent supplier would be required to offer core maintenance sessions for months 7 through 12, and ongoing maintenance sessions should the beneficiary remain eligible for these services.

We also are soliciting public comments on a potential future policy to require a specific class size limit for MDPP sessions. While we acknowledge that MDPP services may be successfully furnished in group settings, we believe that it is important to ensure that the group’s
size is appropriately set such that each beneficiary gains the necessary interaction with the coach furnishing the session to properly learn the curriculum. We considered different mechanisms to ensure this program objective, and are requesting public comments on considerations to date. The mechanism that currently seems most viable would require a limitation on the number of total attendees in a given session taught by an individual coach. Based on CDC’s experience with the DPP program and review of the literature on appropriate class sizes for educational settings, we considered including a class size limitation of 30 participants per coach in a given session (including Medicare beneficiaries). Given that limited data currently exist on this type of requirement among DPP sessions, we are soliciting public comments on what an appropriate class size limitation would be, including any evidence to support such a proposal.

Furthermore, we are soliciting public comments on how MDPP suppliers who furnish sessions in no specific sequential order and allow drop-ins would balance the requirement of providing beneficiary access with a class size requirement for a given session. For example, if a supplier offers classes multiple times a week and gives beneficiaries flexibility regarding when to participate, we questioned whether a certain class size limitation could force a supplier to turn away a beneficiary seeking to attend a session at a time when attendance is high, and in so doing potentially discourage continued use of the set of MDPP services. In addition, we are unsure of any implications that would result from establishing a class size restriction for MDPP services while acknowledging that MDPP beneficiaries may participate in DPP sessions with non-Medicare beneficiaries who may not face the same class size limitation. Given these considerations, we are soliciting public comments on how we could structure this proposal in the future that would achieve the programmatic goals of effectively furnishing the DPP curriculum to Medicare beneficiaries in a manner and setting that contributes to positive behavioral changes
and ultimately less progression to type 2 diabetes. In providing comments on this approach, we encourage the submission of data and evidence to justify what specific class size would be appropriate for MDPP suppliers.

(5) Disclosure

We are proposing, at §424.205(d)(11), that MDPP suppliers must provide information about the MDPP expanded model to each beneficiary to whom it furnishes MDPP services as specified by CMS. This includes detailed information on coverage for the set of MDPP services, the once-per-lifetime limit, on eligibility requirements, and the MDPP supplier standards. We recognize that many aspects of the MDPP expanded model are novel for both beneficiaries and suppliers, and we desire that both parties are well informed. Therefore, we believe that requiring the supplier to fully disclose information about the MDPP expanded model, coverage, and the MDPP supplier standards will help inform all parties. We intend to provide a specific template for the MDPP supplier to use to disclose this information to the beneficiaries. For this reason, we do not believe that requiring this type of disclosure places a significant burden on the supplier. While we believe that this approach will help to address the policy goals of the MDPP expanded model, we are inviting public comments on this approach, particularly upon the provision of a standard CMS disclosure notification as compared to CMS providing MDPP suppliers with information they could use to their own disclosure notification materials. Along these lines, we would like to highlight that we also intent to publish information on MDPP in the 2019 Medicare & You Handbook.

We invite public comments on these proposals.

(6) Beneficiary Complaints
We are proposing that MDPP suppliers must answer Medicare beneficiaries’ questions about MDPP services and respond to MDPP related complaints within a reasonable timeframe in proposed §424.205(d)(12). We also are proposing that MDPP suppliers implement a complaint resolution protocol and maintain documentation of all beneficiary contact regarding such complaints, including the name and Medicare Beneficiary Identifier of the beneficiary, a summary of the complaint, related correspondences, notes of actions taken, and the names and/or NPIs of individuals who took such action on behalf of the MDPP supplier. We are proposing that this information must be kept at a supplier’s administrative location and made available to CMS or its contractors upon request. These records would adhere to the same recordkeeping requirements in §424.205(g), and therefore, would need to be maintained for 10 years. While other records are typically required to be held only for 7 years (per §424.516(f)), given that the MDPP expanded model includes beneficiary engagement incentive (described further in section III.K.2.f.v.) which typically requires an extended documentation requirement, we considered it important to align all recordkeeping requirements for the MDPP expanded model. As noted earlier in this section, we are proposing at §424.205(d)(15) that an MDPP supplier must allow CMS or its agents to conduct recordkeeping reviews to ascertain the supplier’s compliance with these standards, as well as documentation requirements as outlined in §424.205(g).

We believe our proposal that MDPP suppliers must answer, respond to, and document beneficiary complaints and resolutions establishes a tracking mechanism to determine whether or not suppliers are adequately addressing beneficiary concerns. We find this requirement particularly important given that complaint procedures provide a good way to ensure best practices by suppliers. Moreover, DMEPOS supplier standards contain a requirement regarding maintaining complaint procedures. Although we acknowledge that this method requires the
MDPP suppliers to self-attest to complaints, requiring such documentation as a required Medicare standard can help to build accountability to following through with complaint resolution. Additionally, mandating that suppliers take and maintain records of complaints may help to address situations where beneficiaries raise issues directly to us after failing to receive resolution from the supplier directly.

We believe that requiring this documentation would provide an additional mechanism for us to ensure that the supplier is fully disclosing information pertinent to the supplier standards, specifically those regarding beneficiary access, and other concerns. As an additional benefit of this policy, if a beneficiary is denied access, the MDPP supplier would be required to demonstrate the reasoning behind this approach, and we could have an opportunity to review if this reasoning complied with the proposed standard under §424.205(d)(8).

This approach is consistent with supplier standards for other Medicare suppliers, including those for Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers. Given that CMS has imposed similar standards regarding supplier responsibility for addressing beneficiaries’ complaints among other supplier types, we do not believe that requiring a similar such requirement poses an undue burden on MDPP suppliers. Rather, we believe that this approach can facilitate beneficiary satisfaction with the services suppliers furnish by requiring that beneficiary complaints are acknowledged, resolved, and tracked appropriately. We believe that this approach will help ensure that the supplier is meeting beneficiaries’ needs as they relate to the MDPP expanded model. In addition, we believe that this will help ensure the integrity of the MDPP expanded model.

We invite public comments on these proposals.

(7) MDPP Expanded Model Evaluation Compliance
In the CY 2017 PFS final rule, we finalized a requirement for MDPP suppliers to maintain and submit to CMS a crosswalk file that documented how the beneficiary identifiers submitted to CMS for billing and the beneficiary identifiers submitted to CDC for session-level performance data linked to the same beneficiary as a documentation retention and provision requirement (existing §424.59(b), proposed to be redesignated and amended as §424.205(e) in this proposed rule). CMS will use this crosswalk for evaluation purposes so CMS can review session level data that MDPP suppliers provide to CDC to supplement the claims data we receive directly from MDPP suppliers. We indicated that we would provide additional information on format and frequency of this reporting requirement in future rulemaking or administrative guidance as appropriate. We are proposing the maintenance and submission of the crosswalk as an MDPP supplier standard and are providing additional details regarding the format and frequency.

We are proposing that the crosswalk file would contain Medicare Health Insurance Claims Numbers or Medicare Beneficiary Identifiers and the unique participant identifier assigned by the organization, for the purposes of CDC performance data reporting, for each beneficiary receiving MDPP services (proposed §424.205(d)(13)). Beneficiaries for whom at least one Medicare claim was submitted by an MDPP supplier would be required to be included in the crosswalk. We are proposing that the crosswalk be supplied to CMS, or our contractor, beginning 6 months after the organization begins furnishing MDPP services, and quarterly thereafter. The crosswalk would be maintained in a spreadsheet (for example, an Excel file or a CSV file), in a form and manner as specified by CMS. We are inviting public comments on this approach.
Additionally, to enable evaluation of MDPP services for a beneficiary’s entire MDPP services period (that is, up to 3 years), we are proposing that MDPP suppliers must submit performance data for any beneficiaries who attend ongoing maintenance sessions in a manner and form as specified by CMS (proposed §424.205(d)(14)). This proposal serves to ensure that MDPP suppliers provide session-level data for ongoing maintenance sessions that are consistent with the data they are already providing to CDC for the core MDPP services period. This requirement is necessary given that session-level performance data plays a critical role in the Innovation Center’s evaluation of the entirety of the MDPP expanded model. Without such data, the Innovation Center would lack any streamlined method of obtaining session-level data for ongoing maintenance sessions furnished to MDPP beneficiaries. We are proposing that this performance data must align with the performance date elements as required by CDC for the DPRP standards. We are soliciting public comments on this approach.

v. MDPP Supplier Revalidation

In the CY 2017 PFS final rule, we specified that newly enrolling MDPP suppliers as high categorical risk in accordance with §424.518(c), but we did not address the risk level of MDPP suppliers upon revalidation. Section 6401(a) of the Affordable Care Act established that all Medicare suppliers must revalidate their enrollments as a program integrity measure. Upon revalidation, suppliers are screened for their continued enrollment in Medicare. While MDPP suppliers enroll at the high risk level, we are proposing, at §424.205(b)(3)(ii), that MDPP suppliers would revalidate under a moderate risk level in accordance with §424.518(b). We believe that this approach is appropriate, given that fingerprint-based criminal history record checks through the Federal Bureau of Investigation’s Integrated Automated Fingerprint Identification System requirement for “high” categorical risk and will have already been
completed upon initial enrollment. In addition, we believe that this approach is appropriate, given its consistency with other providers and suppliers who initially enroll under “high” categorical risk, but revalidate under “moderate” categorical risk, such as DMEPOS suppliers and Home Health Agencies. We also are proposing, at §424.205(b)(6), as a condition of enrollment, that MDPP suppliers must agree to revalidate their enrollment every 3 years, consistent with DMEPOS suppliers who are initially screened under “high” categorical risk screening level. While we believe that this approach is appropriate for MDPP suppliers, we welcome public comments on these proposals. Interested parties can learn more information on revalidation available on the CMS website at https://www.cms.gov/medicare/provider-enrollment-and-certification/medicareprovidersuponroll/revalidations.html.

We invite comment on the proposed risk level upon revalidation, as well as the frequency with which MDPP suppliers must revalidate their enrollment.

vi. Documentation Retention and Provisions Requirements

We are proposing that the following requirements would apply to records related to a MDPP supplier’s compliance with the MDPP expanded model (codified at §424.59(b), redesignated as amended at §424.205(g)). We believe that these proposals will increase supplier recordkeeping accuracy, and clarify documentation retention requirements. Specifically, we are proposing that an MDPP supplier must:

- Provide to CMS or its contractors, the OIG, and the Comptroller General or their designee(s) scheduled and unscheduled access to all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the supplier’s compliance with MDPP requirements, including the MDPP expanded model
requirements for in-kind beneficiary incentive engagements found in §424.210 in the event that the MDPP supplier chooses to offer such incentives to any MDPP beneficiary.

- Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the MDPP beneficiary’s receipt of MDPP services furnished by the MDPP supplier or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

  ++ CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the MDPP supplier at least 30 calendar days before the normal disposition rate; or

  ++ There has been a dispute or allegation of fraud or similar fault, as defined at §405.902, against the MDPP supplier, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

We believe these modifications increase the likelihood of operationalizing MDPP program integrity strategies that include audits, evaluations, inspections, or investigations, and that they provide additional clarity on documentation retention for ongoing program integrity. In addition, in the CY 2017 PFS established supplier requirements for documentation and recordkeeping (codified at §424.59(b), proposed to be redesignated and amended at §424.205(g). In this proposed rule, we are modifying these requirements to improve clarity. We are proposing at §424.205(g)(1) and (g)(2) to require that documentation must be established contemporaneous to the furnished MDPP services, which we believe is important for accuracy. We are also proposing that for the initial core session, these records must include the following organizational information:
- The organizational name, CDC DPRP organization number, and organizational NPI;
- Basic beneficiary information including but not limited to beneficiary name, HICN, and age; and
- Evidence that each such beneficiary satisfied the eligibility requirements under §410.79(c) at the time of service.

For each additional session, we propose that these records must include:

- Documentation of the type of session, whether a core session, a core maintenance session, an ongoing maintenance session, an in-person make-up session, or a virtual make-up session.
- Identification of which CDC-approved DPRP curriculum was associated with each session.
- The NPI of the coach who furnished the session.
- The date and place of service of the session.
- Each MDPP’s beneficiary’s weight and date weight taken, in a form and manner as specified by CMS.

We believe that this information will play an important role in documenting the provision of MDPP services and fidelity to the requirements established for the expanded model. Finally, at §424.205(g)(3), we are proposing that MDPP suppliers must maintain and handle any beneficiary Personally Identifiable Information (PII) and Personal Health Information (PHI) in compliance with HIPAA, other state and federal privacy laws, and CMS standards. We believe these proposals will improve supplier recordkeeping accuracy and lessen the possibility of incomplete records and supplier recordkeeping variations.
We are inviting public comments on our proposed documentation and maintenance of records requirements, including whether additional or different requirements may provide better program integrity safeguards.

f. Beneficiary Engagement Incentives under the MDPP Expanded Model

We believe that the MDPP expanded model would encourage MDPP suppliers to furnish high quality and engaging health behavior change services to MDPP beneficiaries that lead to improved beneficiary health and reductions in Medicare spending. We further believe that one mechanism that may be useful to the MDPP suppliers in achieving these goals would be allowing MDPP suppliers to furnish certain in-kind items and services to their MDPP beneficiaries during the core services period and ongoing services period (described at proposed §410.79(c)(2)). Under such an approach, the costs of these beneficiary engagement incentives would be borne by the MDPP supplier. However, we believe that certain conditions on these incentives are necessary to ensure that they would be furnished solely for the purpose of achieving the MDPP goal of engaging beneficiaries in making sustainable, healthy behavior changes to reduce their risk of type 2 diabetes.

We are proposing to establish the rules governing the furnishing of beneficiary engagement incentives to MDPP beneficiaries under the MDPP expanded model at new §424.210. As discussed in section III.K.2.a. of this proposed rule, we are proposing that MDPP services would be available beginning on April 1, 2018. Therefore, because there would be no MDPP beneficiaries who could receive beneficiary engagement incentives from MDPP suppliers until on or after April 1, 2018, we are proposing that the effective date of §424.210 would be April 1, 2018.

i. Definitions Specific to Beneficiary Engagement Incentives
We are proposing that if an MDPP supplier offers an in-kind beneficiary engagement incentive, the item or service offered as an incentive must be furnished by an MDPP supplier to a MDPP beneficiary during the engagement incentive period. An engagement incentive period would begin when an MDPP supplier furnishes any MDPP service to an MDPP beneficiary. As proposed at §424.210(a), the term “engagement incentive period” means the period of time during which an MDPP supplier may furnish in-kind beneficiary engagement incentives to a given MDPP beneficiary to whom the MDPP supplier is furnishing MDPP services. The engagement incentive period would end upon the earliest of the following: the beneficiary’s MDPP services period ends (as specified in proposed §410.79(c)(3)) for any reason; the MDPP supplier knows the MDPP beneficiary will no longer be receiving MDPP services from the MDPP supplier; or the MDPP supplier has not had direct contact, either in person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period.

We are proposing that items and services may only be furnished as in-kind beneficiary engagement incentives during the engagement incentive period. This is to ensure that the flexibilities that MDPP suppliers would be afforded under these proposed regulations to furnish free items and services to Medicare beneficiaries only apply while the beneficiary is an MDPP beneficiary being offered MDPP services by that MDPP supplier. Once the MDPP beneficiary’s engagement incentive period ends with an MDPP supplier, all existing laws and regulations would apply to the furnishing of free items and services to a Medicare beneficiary by the entity that is an MDPP supplier. Limiting the furnishing of beneficiary engagement incentives under the MDPP expanded model to the engagement incentive period with a particular MDPP supplier serves as a safeguard against the furnishing of free items and services to Medicare beneficiaries.
to steer them toward particular providers, suppliers, or other services, rather than to engage MDPP beneficiaries in healthy behavior changes that reduce their incidence of type 2 diabetes.

During the course of the MDPP services period, an MDPP beneficiary may begin and end multiple engagement incentive periods, and, to the extent feasible, the MDPP beneficiary would not be in more than one engagement incentive period at the same time. For example, where, after receiving MDPP services from MDPP supplier A, an MDPP beneficiary notifies MDPP supplier A that he or she has chosen to receive MDPP services from MDPP supplier B and subsequently receives MDPP services from MDPP supplier B, the first engagement incentive period ends when MDPP supplier A is told by the MDPP beneficiary that he or she will no longer attend MDPP services with MDPP supplier A. A new engagement incentive period begins when the MDPP beneficiary receives his or her first MDPP service from MDPP supplier B. Additionally, where an MDPP beneficiary begins an engagement incentive period with an MDPP supplier and the engagement incentive period has ended because the MDPP supplier has not had direct contact, either in person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for 90 consecutive days during the MDPP services period, should that MDPP beneficiary receive MDPP services from that MDPP supplier on day 100, a new engagement incentive period would begin.

These proposals for the definitions specific to beneficiary engagement incentives are included at proposed §424.210(a). We are inviting public comments on these proposed definitions specific to furnishing in-kind beneficiary engagement incentives.

ii. General Conditions for Beneficiary Engagement Incentives

We are proposing, at §424.210(b), that an MDPP supplier may choose to furnish items or services as in-kind beneficiary engagement incentives to an MDPP beneficiary only during the
engagement incentive period, subject to a number of additional conditions as program safeguards. Under this proposal, the in-kind items and services furnished as beneficiary engagement incentives under the MDPP expanded model would not be Medicare-covered items or services.

We are proposing that the engagement incentive must be furnished directly by an MDPP supplier or by an agent of the MDPP supplier under the MDPP supplier’s direction and control, such as a coach, to an MDPP beneficiary. As established in the §410.79(b) in the CY 2017 PFS final rule, coach refers to an individual who furnishes MDPP services on behalf of an MDPP supplier as an employee, contractor, or volunteer. We considered whether this policy on beneficiary engagement incentives should extend to entities other than MDPP suppliers and their agents that may refer to or furnish MDPP services during an engagement incentive period. However, given that MDPP suppliers maintain the responsibility to ensure the integrity of MDPP programs and would be best positioned to comply with beneficiary engagement incentive documentation and technology retrieval requirements proposed at §424.210(e) and (c), respectively, we believe that they are best suited to furnished beneficiary engagement incentives.

We are proposing that the item or service furnished as a beneficiary engagement incentive must be reasonably connected to the CDC-approved curriculum taught by an MDPP supplier to an MDPP beneficiary during a core session, a core maintenance session, or an ongoing maintenance session. For example, under this proposal, an MDPP supplier could furnish beneficiary engagement incentives such as gym memberships to reduce barriers associated with beneficiary achievement of physical activity recommended as part of the CDC-approved curriculum, but they could not furnish theater tickets, which would bear no reasonable connection to the CDC-approved curriculum. Similarly, MDPP suppliers may offer incentives
such as onsite child care when the MDPP beneficiary attends MDPP services or transportation vouchers to the site of MDPP services that may reduce barriers to beneficiary attendance at MDPP services, but they could not furnish attendance awards such as movie tickets or retail gift cards, which would have no reasonable connection to the CDC-approved curriculum. Likewise, this proposal would allow MDPP suppliers to furnish equipment that is reasonably necessary for the curriculum being taught to the beneficiary, such as digital scales to track and document patient weight or pedometers to track physical activity, but not broadly used technology that is more valuable to the beneficiary, such as a smartphone. If an MDPP supplier were to furnish a smartphone at no cost to an MDPP beneficiary, a reasonable inference arises that the technology would not be reasonably connected to the curriculum being taught to the beneficiary. Among other things, this safeguard precludes incentives that might serve to induce beneficiaries inappropriately to receive other services than MDPP services from the MDPP supplier.

We also are proposing that the beneficiary engagement incentive must be a preventive care item or service, or an item or service that advances a clinical goal for an MDPP beneficiary as described in section III.K.2.f.iv. of this proposed rule by engaging him or her in better managing his or her own health. This ensures that a relationship between the incentive and the goals of the MDPP expanded model exists so that the beneficiary engagement incentive is necessary for testing the expanded MDPP model. Under this proposed condition, we note that beneficiary engagement incentives may not be offered to an MDPP beneficiary as a reward for achievement of a specified outcome, such as losing weight or attending a certain number of sessions, unless the beneficiary engagement incentive meets all the proposed conditions, including that it is reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, a core maintenance session, or an ongoing maintenance
session by the MDPP supplier and that it is a preventive care item or service or it advances a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health. Furnishing in-kind patient engagement incentives upon achievement of an outcome may not advance a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health unless there are clinical goals that the incentive itself can continue to advance.

We are further proposing that the item or service furnished as a beneficiary engagement incentive must not be tied to the receipt of items or services outside the MDPP services, and that the item or service must not be tied to the receipt of items or services from a particular provider, supplier, or coach. These provisions provide safeguards against the furnishing of in-kind beneficiary engagement incentives to steer beneficiaries toward certain providers, suppliers, or coaches for services outside MDPP services.

We note that in some circumstances, an item or service may be linked to an MDPP supplier and be offered to the MDPP supplier’s MDPP beneficiaries as part of the CDC-approved curriculum that must be furnished during the MDPP services period, rather than being offered to steer the MDPP beneficiary to a particular provider, supplier, or coach. In these situations, we believe the item or service may be furnished as a beneficiary engagement incentive without violating the requirement that the item or service not be tied to the receipt of the items or services from a particular provider, supplier, or coach. For instance, where an MDPP supplier offers a gym membership as a beneficiary engagement incentive, we understand that the gym membership must be tied to a particular supplier of services so that the beneficiary can use the membership. However, in this case, the gym membership would be linked to the MDPP supplier that, in compliance with the curriculum that must be furnished during the MDPP
services period, is teaching MDPP beneficiaries how to utilize a physical fitness regime to meet
the MDPP goal of reducing an MDPP beneficiary’s risk of developing diabetes, rather than being
furnished to steer the MDPP beneficiary to a particular supplier. Therefore, we believe that gym
memberships may be furnished as a beneficiary engagement incentive without violating the
requirement that the item or service not be tied to the receipt of items or services from a
particular provider, supplier, or coach as long as the gym membership is reasonably connected to
the CDC-approved curriculum and not being furnished to steer the MDPP beneficiary to a
particular supplier.

We are proposing that, in general, the availability of the items or services furnished as
beneficiary engagement incentives must not be advertised or promoted as in-kind beneficiary
engagement incentives available to an MDPP beneficiary receiving MDPP services from the
MDPP supplier. However, an MDPP beneficiary may be made aware of the availability of the
items or services at the time the MDPP beneficiary could reasonably benefit from them during
the engagement incentive period. This condition provides a safeguard against the advertisement
of in-kind patient engagement incentives to beneficiaries based on their perceived ability to meet
the performance goals of attendance and weight loss as described at proposed §414.84(a) and
associated with the MDPP performance payments proposed at §414.84(b). The proposed
payment structure for MDPP services largely relies on the achievement of these performance
goals. Therefore, advertising patient engagement incentives to encourage participation of
MDPP-eligible beneficiaries most likely to meet the attendance and weight loss performance
goals could produce financial gain for MDPP suppliers that is not related to the quality and
efficacy of the MDPP supplier’s MDPP services.
In addition, prohibiting the advertisement or promotion of in-kind beneficiary engagement incentives available to an MDPP beneficiary receiving MDPP services from the MDPP supplier except that an MDPP beneficiary may be made aware of the availability of the items or services at the time the MDPP beneficiary could reasonably benefit from them during the engagement incentive period provides a safeguard against using the incentive to steer a beneficiary toward a particular MDPP supplier. Beneficiaries would not be made aware of the availability of beneficiary engagement incentives until the MDPP beneficiary was in an engagement incentive period, which would begin when an MDPP supplier furnished its first MDPP service to the beneficiary. At that point in time, the beneficiary would have already selected that MDPP supplier to furnish his or her MDPP services so the incentive could not be used to steer the beneficiary to that MDPP supplier. We note that we do not intend for beneficiary engagement incentives proposed for the MDPP expanded model to alter an MDPP supplier’s market share for an MDPP or non-MDPP item or service.

Finally, we are proposing that the cost of the items or services offered as in-kind beneficiary engagement incentives must not be shifted to another Federal health care program, as defined at section 1128B(f) of the Act. This requirement affirms that the cost of any beneficiary engagement incentive offered by an MDPP supplier is the sole responsibility of the MDPP supplier, and the furnishing of a beneficiary engagement incentive, for instance, must not result in increased payments to the MDPP supplier by Federal health care programs for other items or services.

These proposals for the general conditions for in-kind beneficiary engagement incentives are included at proposed §424.210(b). We are inviting public comments on these proposed
general conditions for furnishing beneficiary engagement incentives. In addition, we are inviting
public comments on additional or alternative program integrity safeguards.

iii. Technology Furnished to a MDPP Beneficiary

In some cases, items or services involving technology may be useful as beneficiary
engagement incentives because they can advance a clinical goal of the MDPP expanded model
by engaging an MDPP beneficiary in managing his or her health. However, we believe specific
enhanced safeguards are necessary for these items and services to prevent abuse.

First, we are proposing that items or services involving technology furnished by an
MDPP supplier to its MDPP beneficiary may not, in the aggregate, exceed $1,000 in retail value
for any one MDPP beneficiary. We believe that this proposed limit is appropriate, in
conjunction with our proposed enhanced requirements for items of technology with a retail value
greater than $100 as discussed subsequently in this section. The proposed $1,000 limitation
would allow sufficient MDPP supplier flexibility to furnish items or services involving
technology as beneficiary engagement incentives to improve the likelihood of the beneficiary’s
achievement and maintenance of the required minimum weigh loss. The proposed limitation
would not allow the furnishing of items of technology that in the aggregate constitute an
excessively high value to the beneficiary that could increase the risk that the items of technology
would not be in compliance with all of the proposed requirements for beneficiary engagement
incentives.

For example, under this proposal, an MDPP beneficiary who begins receiving MDPP
services from an MDPP supplier and who, after receiving MDPP services from that MDPP
supplier, is furnished items or services of technology with a total retail value of $1,000 may not
receive additional items or services of technology from that MDPP supplier. Therefore, an
MDPP beneficiary may receive from a MDPP supplier a tablet valued at $700 that is preloaded with weight loss and fitness tracking apps that would support the beneficiary’s weight loss goals under the MDPP expanded model and also receive from the same MDPP supplier a fitness tracking watch valued at $200 that uploads and monitors fitness data to the tablet, but he or she could not then receive additional items of technology from the MDPP supplier with an aggregate retail value greater than $100 as this would exceed the $1,000 limit.

In addition, if the same MDPP beneficiary chooses to receive MDPP services from another MDPP supplier, the subsequent supplier is under no obligation to determine the value of any items or services of technology furnished to the MDPP beneficiary by other MDPP suppliers, and may furnish items or services of technology to the MDPP beneficiary so long as those items or services furnished by the subsequent supplier are the minimum necessary to advance a clinical goal for the MDPP beneficiary, are furnished during the engagement incentive period, and do not, in aggregate, exceed $1,000 in retail value. We note that, while items of technology must be furnished to the MDPP beneficiary during an engagement incentive period, the $1,000 limit for items of technology that may be furnished to any one MDPP beneficiary by any one MDPP supplier is not otherwise affected by the engagement incentive period. For example, if an MDPP beneficiary begins and ends multiple engagement incentive periods with the same MDPP supplier as described in section III.K.2.f.i. of this proposed rule, the $1,000 limit for items of technology would not “reset” at the beginning of a new engagement incentive period with that MDPP supplier.

We are further proposing that items or services involving technology furnished to an MDPP beneficiary must be the minimum necessary to advance a clinical goal for MDPP beneficiaries as discussed in section III.K.2.f.iv. of this proposed rule.
We are proposing enhanced requirements for items of technology exceeding $100 in retail value as an additional safeguard against misuse of these items as beneficiary engagement incentives. We believe it would be inappropriate for MDPP suppliers to furnish items of technology with a retail value of over $100 for beneficiaries’ permanent use because the high value of these items could unduly influence the beneficiary to continue to receive MDPP services from that supplier, or to receive items or services from the supplier other than MDPP services. Therefore, we are proposing that items of technology with a retail value of over $100 would remain the property of the MDPP supplier and be retrieved from the MDPP beneficiary at the end of the engagement incentive period. We do not believe that this requirement would substantially increase the administrative burden on MDPP suppliers because a central facilitator of the success of an MDPP beneficiary in meeting MDPP performance goals is the MDPP supplier’s ability to maintain contact with the MDPP beneficiary and engage him or her in MDPP services. We note that items of technology with a retail value of $100 or less could be furnished as beneficiary engagement incentives and would remain the property of the beneficiary. In the case of these items of a technology with a lower retail value, we believe the administrative burden of retrieving these items would outweigh the program integrity benefits of retrieval.

We are further proposing that the MDPP supplier must document all technology retrieval attempts, including the ultimate date of retrieval. However, because we understand that MDPP suppliers may not always be able to retrieve these items, such as when a beneficiary dies or moves to another geographic area, documented, diligent, good faith attempts to retrieve items of technology would be deemed to meet the retrieval requirement.
Our proposals for enhanced requirements for technology furnished to MDPP beneficiaries as beneficiary engagement incentives under the MDPP expanded model are included at proposed §424.210(c). We are inviting public comments on our proposed requirements for beneficiary engagement incentives that involve technology and welcome comments on additional or alternative program integrity safeguards for this type of beneficiary engagement incentive, including whether the financial thresholds proposed in this section are reasonable, necessary, and appropriate.

iv. Clinical Goals of the MDPP Expanded Model

As established at §410.79(b) in the CY 2017 PFS final rule, MDPP services furnished to MDPP beneficiaries must follow a CDC-approved curriculum, which outlines required and recommended topics for structured health behavior change sessions offered as MDPP services with the goal of preventing diabetes through long-lasting health behavior change. MDPP suppliers seeking recognition under the CDC’s DPRP must furnish either the CDC-preferred curriculum, based on the current evidence base, or may develop their own curriculum. MDPP suppliers who wish to develop their own curriculum must submit it to the CDC for approval. This requirement ensures that all curricula furnished to MDPP beneficiaries meet the DPRP’s curriculum content requirements and are based on evidence from efficacy and effectiveness trials consistent with the current evidence base. To be consistent with the current evidence base, all curricula offered by MDPP suppliers must furnish MDPP services focused on the overarching goal of preventing type 2 diabetes in persons at high risk for diabetes because they have prediabetes. This requires MDPP suppliers to emphasize the need to make lasting health behavior changes, rather than simply completing a one-time set of MDPP services that result in the required minimum weight loss during the MDPP services period. MDPP services must also
emphasize long-term improvements in nutrition and physical activity that contribute to beneficiaries sustaining weight loss. Therefore, we believe that in-kind patient engagement incentives may appropriately be furnished to support and motivate MDPP beneficiaries in achieving dietary and health behavior change and to teach MDPP beneficiaries to problem-solve strategies to overcome challenges to maintaining weight loss and healthy behaviors, as well as to assist MDPP beneficiaries in meeting the attendance and weight loss performance goals of the MDPP expanded model.

Therefore, we are proposing that the following would be the clinical goals of the MDPP expanded model, which may be advanced through beneficiary engagement incentives:

- Beneficiary attendance at MDPP core sessions, core maintenance sessions, or ongoing maintenance sessions during the MDPP services period.
- Beneficiary weight loss.
- Long-term dietary change for the beneficiary.
- Beneficiary adherence to long-term health behavior changes.

We note that under this proposal, the MDPP supplier may not furnish multiple free meals or meal replacement services to an MDPP beneficiary over a substantial portion of the engagement incentive period because such a practice would not advance a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health.

When a beneficiary engagement incentive does not qualify as a preventive care item or service, our proposals for the clinical goals of the MDPP expanded model that a beneficiary engagement incentive must be intended to advance are included at proposed §424.210(d). We are inviting public comments on our proposed clinical goals of the MDPP, as well as whether the advancement of additional or different clinical goals through beneficiary engagement incentives
may better advance the overarching goals of the MDPP expanded model, while maintaining appropriate program integrity safeguards.

v. Documentation of Beneficiary Engagement Incentives

As a program safeguard against misuse of beneficiary engagement incentives under the MDPP expanded model, we are proposing that, in addition to the documentation requirements for MDPP suppliers at proposed §424.205(g), MDPP suppliers must maintain documentation of items and services furnished as beneficiary engagement incentives that individually exceed $25 in retail value. We recognize that an MDPP beneficiary could receive many incentives that are each of low dollar value but in the aggregate constitute an excessively high value to the beneficiary. Therefore, we believe it is important to incorporate a documentation threshold at a modest level for all beneficiary incentives in order to monitor compliance with the proposed conditions for furnishing these items and services. Moreover, we believe the proposed $25 retail value threshold strikes an appropriate balance between beneficiary and program protections and MDPP supplier administrative burden.

In addition, we are proposing to require that the documentation must be established contemporaneously with the furnishing of the items and services and must include at least the date the incentive was furnished; the identity of the beneficiary to whom the item or service was furnished; the agent of the supplier who furnished the item or service if applicable; a description of the item or service; the retail value of the beneficiary engagement incentive; and documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period.

In addition to the proposed requirements in the previous paragraph, we are further proposing that the documentation regarding items or services furnished to the MDPP beneficiary
for use on an ongoing basis during the engagement incentive period, including items of technology exceeding $100 in retail value, must also include contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary possesses or has access to the item or service furnished by the MDPP supplier. For example, if an MDPP supplier furnishes a gym membership to an MDPP beneficiary, the MDPP supplier must maintain contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary has access to the gym via the membership furnished by the MDPP supplier.

In addition to the above requirements, we are further proposing that the documentation regarding items of technology exceeding $100 in retail value that MSPP suppliers are required to retrieve from the MDPP beneficiary must also include contemporaneous documentation of any attempts to retrieve the item of technology furnished by the MDPP supplier from the MDPP beneficiary as required at proposed §424.210(c)(3)(ii). We reiterate that under our proposal documented, diligent, good faith attempts to retrieve items of technology would be deemed to meet the retrieval requirement.

Finally, we are proposing that the MDPP supplier must retain and provide access to the required documentation in accordance with proposed §424.205(g).

Table 35 summarizes the proposed documentation requirements for beneficiary engagement incentives under the MDPP expanded model.
TABLE 35: Proposed Beneficiary Engagement Incentive Documentation Requirements

<table>
<thead>
<tr>
<th>Item or service with retail value greater than $25</th>
<th>Documentation Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Contemporaneous documentation that includes at least:</td>
<td></td>
</tr>
<tr>
<td>▪ The date the incentive was furnished.</td>
<td></td>
</tr>
<tr>
<td>▪ The identity of the MDPP beneficiary to whom the item or service was furnished.</td>
<td></td>
</tr>
<tr>
<td>▪ Documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period.</td>
<td></td>
</tr>
<tr>
<td>▪ The agent of the supplier who furnished the item or service, if applicable.</td>
<td></td>
</tr>
<tr>
<td>▪ A description of the item or service.</td>
<td></td>
</tr>
<tr>
<td>▪ The retail value of the item or service.</td>
<td></td>
</tr>
<tr>
<td>• Documentation regarding items or services that are furnished to the MDPP beneficiary for use on an ongoing basis during the engagement incentive period, including items of technology exceeding $100 in retail value, must also include contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary possesses or has access to the item or service furnished by the MDPP supplier.</td>
<td></td>
</tr>
<tr>
<td>• The documentation regarding items of technology exceeding $100 in retail value must also include contemporaneous documentation of any attempt to retrieve the technology.*</td>
<td></td>
</tr>
<tr>
<td>• The MDPP supplier must retain and provide access to the documentation.</td>
<td></td>
</tr>
</tbody>
</table>

* = Items of technology with a retail value greater than $100 remain the property of the MDPP supplier and must be retrieved from the MDPP beneficiary at the end of the engagement incentive period.

Our proposals for the documentation requirements for beneficiary engagement incentives under the MDPP expanded model are included at proposed §424.210(e). We are inviting public comments on our proposed documentation requirements, including whether additional or different documentation requirements may provide better program integrity safeguards.

vi. Compliance with Fraud and Abuse Laws

Certain arrangements between MDPP suppliers and beneficiaries may implicate the civil monetary penalty (CMP) law (sections 1128A(a)(5), (b)(1) and (b)(2) of the Act), or the Federal Anti-kickback statute (section 1128B(b)(1) and (2) of the Act). In many cases, arrangements that
implicate these laws can be structured to comply with them by using existing safe harbors and exceptions. Section 1115A(d)(1) of the Act authorizes the Secretary to waive certain specified fraud and abuse laws as may be necessary solely for purposes of testing of models under section 1115A(b) of the Act. A waiver is not needed for an arrangement that does not implicate the fraud and abuse laws or that implicates the fraud and abuse laws, but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law. Accordingly, pursuant to section 1115A(d)(1) of the Act, the Secretary will consider whether waivers of certain fraud and abuse laws are necessary for the MDPP expanded model. Such waivers, if any, would be promulgated separately from this proposed regulation by OIG (as to sections 1128A and 1128B of the Act), to which the respective authorities have been delegated.

The requirements in the final rule for the MDPP expanded model will bear on the need for and scope of any fraud and abuse waivers that might be granted for the model. Because of the close nexus between the final regulations governing the structure and operations of the MDPP expanded model and the development of any fraud and abuse waivers necessary to carry out the provisions of the model, CMS and OIG may, when considering the need for or scope of any waivers, consider comments submitted in response to this proposed rule and the provisions of the final rule.

3. Virtual DPP and the MDPP Expanded Model

The CDC’s DPRP standards allow evidence-based DPP curricula to be furnished through a variety of modes, including through remote technologies. Similar to the description noted in section III.K.2.c.iv.3 with respect to virtual make-up sessions, virtual DPP refers to any modality, or method of furnishing MDPP services, that is not in person. This includes, but is not limited to:
(1) Furnishing services online where the behavior change program is furnished 100 percent online, with participants accessing course resources and lifestyle coach via a computer, laptop, tablet, smart phone, or other device with internet access. This modality requires an internet connection to participate in all aspects of the DPP;

(2) Furnishing services online with other means of support by a coach (for example, telecommunications, video conferencing). This modality requires an internet connection for some aspects of the DPP, but not all; and

(3) Distance learning, where a coach is present in one location and participants are calling, video-conferencing, or otherwise using telecommunications technology to access the coach from another location. This modality does not require any internet connection for any of the aspects of the DPP.

These types of delivery modes are hereafter referred to as “virtual,” and DPP furnished exclusively through these modes with no in-person delivery is hereafter referred to as “virtual DPP.”

We acknowledge that the public comments in response to the MDPP expanded model in the CY 2017 PFS proposed rule supported the inclusion of virtual DPP in the MDPP expanded model. Many commenters stated that this proposal would increase access to MDPP services, referenced emerging evidence that suggests virtual DPP may be as effective as DPP furnished in a community setting, and stated that virtual delivery may be preferable to some beneficiaries. In the CY 2017 PFS final rule, we deferred policies pertinent to virtual DPP to future rulemaking.

While we propose to allow a limited number of virtual make-up sessions in the MDPP expanded model (discussed in section III.K.2.c.iv.3), we do not propose to include virtual DPP services (that is, DPP furnished exclusively through remote technologies with no in-person
We considered including virtual DPP services in the MDPP expanded model, however, the DPP model test that was used to make the statutorily required determination for expansion did not include virtual DPP services. Instead, we are considering a separate model under CMS’s Innovation Center authority to test and evaluate virtual DPP services. Our intention is that any separate model test of virtual DPP services would run in parallel with the MDPP Expanded Model. Consistent with our regular practice for Innovation Center models, we would release details on the model test for virtual DPP services separately.

We note that some DPP suppliers currently offer DPP services through a combination of in-person and virtual delivery. We only propose to allow this combination of delivery subject to the requirements on virtual make-up sessions discussed in section III.K.2.c.iv.3. The combined-delivery DPP services that are currently offered are intended to offer a participant DPP services through both online and in-person methods. The MDPP expanded model, in contrast, is intended to offer participants in-person DPP services primarily, but allows a limited number of virtual make-up sessions on an individual basis. As discussed in section III.K.2.c.iv.3., there is substantial research on the effectiveness of DPP furnished virtually, and emerging evidence on DPP delivered virtually suggests that virtual delivery can show similarly successful participant weight loss and health benefits to DPP delivered in other settings, including among Medicare-age participants. However, since the DPP model test only included in-person delivery, we propose to limit the number of virtually-delivered make-up sessions to the limits discussed in section III.K.2.c.iv.3.

An organization may furnish separate DPPs where some participants receive only in-person DPP services, others receive only virtual DPP services, and others receive a combination program where some sessions are offered in person and others virtually. If an organization that
offers multiple distinct DPPs through different delivery modes enrolls as an MDPP supplier, we propose that only DPP services furnished in person will be paid in the MDPP expanded model, with the exception of virtual make-up sessions as discussed in section III.K.2.c.iv.3 of this proposed rule.

We invite public comments on these policies.

4. Evaluation

We intend to evaluate the MDPP expanded model using a combination of encounter and claims data to analyze the long-term utilization of services by beneficiaries who have received the MDPP benefit. As discussed in the CY 2017 PFS final rule, we will continue to assess whether the MDPP expanded model is expected to improve the quality of care without increasing spending, reduce spending without reducing the quality of care, or improve the quality of care and reduce spending, and we will terminate or modify the MDPP expanded model if the expanded model is not expected to meet these criteria.

Among other possible questions we might explore, our analysis will specifically look at long-term utilization and expenditures that might suggest subsequent treatment of diabetes. We intend to use beneficiary-level encounter data and program data furnished by CDC and will match these data to Medicare claims using the crosswalk finalized at §424.59(b)(3) of the CY 2017 PFS final rule (proposed to be redesignated and amended at §424.205(d)(13)). As with other Innovation Center model evaluation reports (which are currently published online at https://innovation.cms.gov/Data-and-Reports/index.html), we intend to publish the MDPP evaluation annual reports publicly on a CMS website. We refer readers to the supplier requirements discussed under section III.K.2.e.iv.(7) of this proposed rule for the proposal
regarding supplier compliance with this requirement, as well as specifications on the timing and format of the crosswalk.
L. Request for Information on CMS Flexibilities and Efficiencies

CMS is committed to transforming the health care delivery system--and the Medicare program--by putting an additional focus on patient-centered care and working with providers, physicians, and patients to improve outcomes. We seek to reduce burdens for hospitals, physicians, and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. These are the reasons we are including this Request for Information in this proposed rule.

As we work to maintain flexibility and efficiency throughout the Medicare program, we would like to start a national conversation about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families. We aim to increase quality of care, lower costs improve program integrity, and make the health care system more effective, simple and accessible.

We would like to take this opportunity to invite the public to submit their ideas for regulatory, subregulatory, policy, practice, and procedural changes to better accomplish these goals. Ideas could include payment system redesign, elimination or streamlining of reporting, monitoring and documentation requirements, aligning Medicare requirements and processes with those from Medicaid and other payers, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, support of the physician-patient relationship in care delivery, and facilitation of individual preferences. Responses to this Request for Information could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, physicians, providers, and suppliers. Where practicable, data and specific examples would be helpful. If the proposals involve novel legal questions, analysis regarding CMS’ authority is welcome for
CMS’ consideration. We are particularly interested in ideas for incentivizing organizations and the full range of relevant professionals and paraprofessionals to provide screening, assessment and evidence-based treatment for individuals with opioid use disorder and other substance use disorders, including reimbursement methodologies, care coordination, systems and services integration, use of paraprofessionals including community paramedics and other strategies. We are requesting commenters to provide clear and concise proposals that include data and specific examples that could be implemented within the law.

We note that this is a Request for Information only. Respondents are encouraged to provide complete but concise responses. This Request for Information is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This Request for Information does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this Request for Information and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this Request for Information; all costs associated with responding to this Request for Information will be solely at the interested party’s expense. We note that not responding to this Request for Information does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this Request for Information announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this Request for Information. CMS will not respond to comment submissions in response to this Request for Information in the FY 2018 PFS final rule. Rather, CMS will actively consider all input as we develop future regulatory proposals or future
subregulatory policy guidance. CMS may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders’ written responses. Contractor support personnel may be used to review responses to this Request for Information. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this Request for Information may be used by the Government for program planning on a nonattribution basis. Respondents should not include any information that might be considered proprietary or confidential. This Request for Information should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publically post the public comments received, or a summary of those public comments.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. chapter 35), we are required to publish a 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.

- The accuracy of our burden estimates.

- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements (ICRs): (1) The Medicare Diabetes Prevention Program (MDPP) Expanded Model, (2) the Physician Quality Reporting System (PQRS), (3) appropriate use criteria for advanced diagnostic imaging services, and (4) the Medicare Shared Savings Program.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics’ May 2016 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 36 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

<table>
<thead>
<tr>
<th>Occupation Title</th>
<th>Occupation Code</th>
<th>Mean Hourly Wage ($/hr)</th>
<th>Fringe Benefits and Overhead Costs ($/hr)</th>
<th>Adjusted Hourly Wage ($/hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family and General Practitioner</td>
<td>29-1062</td>
<td>96.54</td>
<td>96.54</td>
<td>193.08</td>
</tr>
</tbody>
</table>

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding the Medicare Diabetes Prevention Program (MDPP) Expanded Model
In §§410.79, 414.84, 424.200, 424.205, 424.210, 424.502, 424.516, 424.518 and 424.55 of this proposed rule, we discuss our proposals to further implement the Medicare Diabetes Prevention Program (MDPP) Expanded Model, which is aimed at preventing the onset of type 2 diabetes among Medicare beneficiaries with prediabetes. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the MDPP expanded model, from the provisions of the PRA. Specifically, this section provides that the provisions of the PRA shall not apply to the testing and evaluation of Innovation Center models or expansions of such models.

2. ICRs Regarding the Physician Quality Reporting System (PQRS) (§414.90)

While this rule proposes to revise our PQRS reporting criteria for the 2016 reporting period to avoid the 2018 payment adjustment, we are not proposing to accept any additional data for the 2016 reporting period. In this regard this rule does not set out any new or revised burden or requirements that would trigger the requirements of the PRA.

3. ICRs Regarding Appropriate Use Criteria for Advanced Diagnostic Imaging Services (§414.94)

This rule proposes to revise §414.94(i)(3) by reiterating the availability of a significant hardship exception for ordering professionals who demonstrate a significant hardship consistent with the criteria listed under §495.102(d)(4)(i), (d)(4)(iii), (d)(4)(iv)(A) or (d)(4)(iv)(B). Consistent with a final rule that published on November 14, 2016 (81 FR 79865 through 79866) the hardship exception process involves the completion of an application which imposes no burden beyond the provision of identifying information and attesting to the applicable information. In this regard, the application is not “information” as defined under 5 CFR 1320.3(h), and therefore, is exempt from requirements of the PRA.
Consistent with section 1834(q)(4)(A) of the Act (as amended by section 218(b) of the PAMA), §414.94(j) proposes to require that ordering professionals consult specified applicable AUC through a qualified clinical decision support mechanism (CDSM) for applicable imaging services ordered on or after January 1, 2019. We propose a one-time burden associated with a possible 6-month voluntary consulting period beginning sometime in 2018, as well as a mandatory annual burden beginning January 1, 2019. Because general practitioners are the largest group of practitioners who order applicable imaging services and would be required to consult AUC under this program we use “family and general practitioner” for our estimates below.

During the 6-month voluntary participation period, we estimate 3,410,000 responses in the form of consultations based on market research from current applicants for the qualification of their CDSMs for advanced diagnostic imaging services. Based on feedback from CDSMs with experience in AUC consultation as well as standards recommended by the Office of the National Coordinator (ONC) and the Healthcare Information Management Systems Society (HIMSS), we estimate it would take 2 minutes at $193.08/hr for a family and general practitioner to use a qualified CDSM to consult specified applicable AUC. Per consultation, we estimate 2 minutes (0.033 hr) at a cost of $6.37 (0.033 hr x $193.08/hr). In aggregate, we estimate a one-time burden of 112,530 hours (0.033 hr x 3,410,000 consultations) at a cost of $21,727,292.40 (112,530 hr x $193.08/hr).

Annually, we estimate 37,510 hours (112,530 hr/3 yr) at a cost of $7,242,430.80 ($21,727,292.40/3 yr). We are annualizing the one-time burden (by dividing our estimates by OMB’s 3-year approval period) since we do not anticipate any additional burden after the 6-month voluntary participation period ends.
Beginning January 1, 2019, we anticipate 43,181,818 responses in the form of consultations based on the aforementioned market research, as well as Medicare claims data for advanced diagnostic imaging services. As noted above, we estimate it would take 2 minutes (0.033 hr) at $193.08/hr for a family and general practitioner to use a qualified CDSM to consult specified applicable AUC. In this regard, we estimate 0.033 hours per consultation at a cost of $6.37 (0.033 hr x $193.08/hr). In aggregate, we estimate an annual burden of 1,425,000 hours (0.033 hr x 43,181,818 consultations) at a cost of $275,139,000 (1,425,000 hr x $193.08/hr).

The consultation requirements and burden will be submitted to OMB for approval under control number 0938-New (CMS-10654).

Consistent with section 1834(q)(4)(B) of the Act, we are also proposing to implement a one-time 6-month voluntary reporting period beginning sometime in 2018, as well as a mandatory annual reporting requirement beginning January 1, 2019. Specifically, §414.94(k) proposes to require that furnishing professionals report on the Medicare claims for advanced diagnostic imaging services, paid for under an applicable payment system (as defined in §414.94(b)) and ordered on or after January 1, 2019, the following information: (1) identify which qualified CDSM was consulted by the ordering professional; (2) identify whether the service ordered would adhere to specified applicable AUC, would not adhere to specified applicable AUC, or whether specified applicable AUC was not applicable to the service ordered; and (3) identify the NPI of the ordering professional (if different from the furnishing professional). The proposed reporting requirement would not have any impact on any Medicare claim forms because the forms’ currently approved data fields, instructions, and burden are not expected to change. Consequently, there is no need for review by OMB under the authority of the PRA.
The timing and implementation of the voluntary consultation and reporting period is dependent on the readiness of the Medicare claims systems to accept and process claims including AUC consultation information. Currently, 99 percent of all Medicare claims are submitted electronically as a result of The Administrative Simplification Compliance Act amendment to section 1862(a) of the Act, which prescribes that no payment may be made under Part B of the Medicare Program for any expenses incurred for items or services for which a claim is received in a non-electronic form. Consequently, absent an applicable exception, paper claims received by Medicare will not be paid. Continued developments in the deployment of CDSMs has produced research and best practices supporting our position that any such changes made to respondent IT systems would be a usual and customary business practice whose burden is exempt from the requirements of the PRA under 5 CFR 1320.3(b).

4. ICRs Regarding the Medicare Shared Savings Program (Part 425)

Section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the Shared Savings Program.

C. Summary of Annual Burden Estimates for Proposed Requirements

<table>
<thead>
<tr>
<th>Regulation Section(s)</th>
<th>OMB Control Number</th>
<th>Respondents</th>
<th>Responses</th>
<th>Burden per Response (hours)</th>
<th>Total Annual Burden (hours)</th>
<th>Labor Cost of Reporting ($/hr)</th>
<th>Total Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>§414.94(j) (voluntary consultations)</td>
<td>0938-New</td>
<td>3,410,000</td>
<td>1,136,666.67 (3,410,000/3)</td>
<td>0.033</td>
<td>37,510</td>
<td>193.08</td>
<td>7,242,431</td>
</tr>
<tr>
<td>§414.94(j) (mandatory)</td>
<td>43,181,818</td>
<td>43,181,818</td>
<td>0.033</td>
<td>1,425,000</td>
<td>193.08</td>
<td>275,139,000</td>
<td></td>
</tr>
</tbody>
</table>

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D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule’s information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.


We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the ADDRESSES section of this proposed rule and identify the rule (CMS-1676-P) and where applicable the ICR’s CFR citation, CMS ID number, and OMB control number. See the DATES and ADDRESSES sections of this proposed rule for further information.

V. Response to Comments

<table>
<thead>
<tr>
<th>Regulation Section(s) consultations)</th>
<th>OMB Control Number</th>
<th>Respondents</th>
<th>Responses</th>
<th>Burden per Response (hours)</th>
<th>Total Annual Burden (hours)</th>
<th>Labor Cost of Reporting ($/hr)</th>
<th>Total Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>--</td>
<td>46,591,818</td>
<td>44,318,485</td>
<td>0.033</td>
<td>1,462,510</td>
<td>193.08</td>
<td>282,381,431</td>
</tr>
</tbody>
</table>

*With respect to the PRA, this rule would not impose any non-labor costs.
Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.
VI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule makes payment and policy changes under the Medicare PFS and makes required statutory changes under the MACRA, ABLE, PAMA, and the Consolidated Appropriations Act of 2016. This final rule also makes changes to payment policy and other related policies for Medicare Part B, Part D, and Medicare Advantage.

B. Overall Impact


Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate, as discussed in this section, that the PFS provisions included in this final rule would redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is “economically significant” as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that,
to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details see the SBA’s website at http://www.sba.gov/content/table-small-business-size-standards (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this final rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

For example, the effects of changes to payment rates for practitioners, other providers, and suppliers are discussed in VI.C. of this proposed rule. Alternative options considered to the proposed payment rates are discussed generally in section VI.F of this proposed rule, while
specific alternatives for individual codes are discussed throughout this rule, especially in section II.H.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold is approximately $148 million. This proposed rule will impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.
Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This proposed rule is subject to the requirements of E.O. 13771 because, if finalized as proposed, it is expected to result in regulatory costs.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities.

As indicated elsewhere in this proposed rule, we are implementing a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and implementing statutory provisions. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compare payment rates for CY 2017 with proposed payment rates for CY 2018 using CY 2016 Medicare utilization. The payment impacts in this proposed rule reflect averages by specialty based on
Medicare utilization. The payment impact for an individual practitioner could vary from the average and would depend on the mix of services he or she furnishes. The average percentage change in total revenues would be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Laboratory Fee Schedule.

The annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula; for details about this formula, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67741 through 67742). Section 101(a) of the MACRA repealed the previous statutory update formula and amended section 1848(d) of the Act to specify the update adjustment factors for calendar years 2015 and beyond. For CY 2018, the specified update is 0.5 percent before applying other adjustments.

Section 220(d) of the PAMA added a new paragraph at section 1848(c)(2)(O) of the Act to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. Under section 1848(c)(2)(O)(ii) of the Act, if the net reduction in expenditures for the year is equal to or greater than the target for the year, reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the PFS in accordance with the existing budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act. Section 1848(c)(2)(O)(iii) of the Act specifies that, if the estimated net reduction in PFS expenditures for the year is less than the target for the year, an amount equal to the target recapture amount shall not be taken into account when applying the
budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act. We estimate the CY 2018 net reduction in expenditures resulting from adjustments to relative values of misvalued codes to be 0.31 percent. Since this amount does not meet the 0.5 percent target established by the Achieving a Better Life Experience Act of 2014 (ABLE) (Division B of Pub. L. 113-295, enacted December 19, 2014), payments under the fee schedule must be reduced by the difference between the target for the year and the estimated net reduction in expenditures, known as the target recapture amount. As a result, we estimate that the CY 2018 target recapture amount will produce a reduction to the conversion factor of -0.19 percent.

To calculate the proposed conversion factor for this year, we multiplied the product of the current year conversion factor and the update adjustment factor by the target recapture amount and the budget neutrality adjustment described in the preceding paragraphs. We estimate the CY 2018 PFS conversion factor to be 35.9903, which reflects the budget neutrality adjustment, the 0.5 percent update adjustment factor specified under section 1848(d)(18) of the Act, and the -0.31 percent target recapture amount required under section 1848(c)(2)(O)(iv) of the Act and described above. We estimate the CY 2018 anesthesia conversion factor to be 22.0353, which reflects the same overall PFS adjustments, as well as an additional adjustment due to an update to the malpractice risk factor for the anesthesia specialty.
**TABLE 38: Calculation of the Proposed CY 2018 PFS Conversion Factor**

<table>
<thead>
<tr>
<th>Conversion Factor in effect in CY 2017</th>
<th>35.8887</th>
</tr>
</thead>
<tbody>
<tr>
<td>Update Factor</td>
<td>0.50 percent (1.0050)</td>
</tr>
<tr>
<td>CY 2018 RVU Budget Neutrality Adjustment</td>
<td>-0.03 percent (0.9997)</td>
</tr>
<tr>
<td>CY 2018 Target Recapture Amount</td>
<td>-0.19 percent (0.9981)</td>
</tr>
<tr>
<td>CY 2018 Conversion Factor</td>
<td>35.9903</td>
</tr>
</tbody>
</table>

**TABLE 39: Calculation of the Proposed CY 2018 Anesthesia Conversion Factor**

<table>
<thead>
<tr>
<th>CY 2017 National Average Anesthesia Conversion Factor</th>
<th>22.0454</th>
</tr>
</thead>
<tbody>
<tr>
<td>Update Factor</td>
<td>0.50 percent (1.0050)</td>
</tr>
<tr>
<td>CY 2018 RVU Budget Neutrality Adjustment</td>
<td>-0.03 percent (0.9997)</td>
</tr>
<tr>
<td>CY 2018 Target Recapture Amount</td>
<td>-0.19 percent (0.9981)</td>
</tr>
<tr>
<td>CY 2018 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment</td>
<td>-0.33 percent (0.9967)</td>
</tr>
<tr>
<td>CY 2018 Conversion Factor</td>
<td>22.0353</td>
</tr>
</tbody>
</table>

Table 40 shows the payment impact on PFS services of the proposals contained in this proposed rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues would be different from those shown in Table 40 (CY 2018 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 40.

- **Column A (Specialty):** Identifies the specialty for which data are shown.

- **Column B (Allowed Charges):** The aggregate estimated PFS allowed charges for the specialty based on CY 2016 utilization and CY 2017 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
● **Column C (Impact of Work RVU Changes):** This column shows the estimated CY 2018 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.

● **Column D (Impact of PE RVU Changes):** This column shows the estimated CY 2018 impact on total allowed charges of the changes in the PE RVUs.

● **Column E (Impact of MP RVU Changes):** This column shows the estimated CY 2018 impact on total allowed charges of the changes in the MP RVUs, which are primarily driven by the required five-year review and update of MP RVUs.

● **Column F (Combined Impact):** This column shows the estimated CY 2018 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.
TABLE 40: CY 2018 PFS Estimated Impact on Total Allowed Charges by Specialty*

<table>
<thead>
<tr>
<th>Specialty</th>
<th>(B) Allowed Charges (mil)</th>
<th>(C) Impact of Work RVU Changes</th>
<th>(D) Impact of PE RVU Changes</th>
<th>(E) Impact of MP RVU Changes</th>
<th>(F) Combined Impact**</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL</td>
<td>$92,628</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>ALLERGY/IMMUNOLOGY</td>
<td>$245</td>
<td>0%</td>
<td>-3%</td>
<td>0%</td>
<td>-3%</td>
</tr>
<tr>
<td>ANESTHESIOLOGY</td>
<td>$2,009</td>
<td>-1%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>AUDIOLOGIST</td>
<td>$66</td>
<td>0%</td>
<td>0%</td>
<td>-1%</td>
<td>-1%</td>
</tr>
<tr>
<td>CARDIAC SURGERY</td>
<td>$311</td>
<td>0%</td>
<td>0%</td>
<td>-1%</td>
<td>-2%</td>
</tr>
<tr>
<td>CARDIOLOGY</td>
<td>$6,671</td>
<td>0%</td>
<td>-1%</td>
<td>-1%</td>
<td>-2%</td>
</tr>
<tr>
<td>CHIROPRACTOR</td>
<td>$772</td>
<td>0%</td>
<td>1%</td>
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<td>1%</td>
</tr>
<tr>
<td>CLINICAL PSYCHOLOGIST</td>
<td>$756</td>
<td>0%</td>
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<td>2%</td>
</tr>
<tr>
<td>CLINICAL SOCIAL WORKER</td>
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<td>0%</td>
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<td>3%</td>
</tr>
<tr>
<td>COLON AND RECTAL SURGERY</td>
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<td>0%</td>
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<td>-1%</td>
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<td>-6%</td>
</tr>
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<td>-1%</td>
<td>-1%</td>
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<td>$477</td>
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<tr>
<td>HEMATOLOGY/ONCOLOGY</td>
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<td>-2%</td>
</tr>
<tr>
<td>INFECTIOUS DISEASE</td>
<td>$651</td>
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<td>1%</td>
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<tr>
<td>INTERNAL MEDICINE</td>
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<td>0%</td>
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<tr>
<td>INTERVENTIONAL PAIN MGMT</td>
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<tr>
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<td>MULTISPECIALTY CLINIC/OTHER PHYS</td>
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<td>0%</td>
</tr>
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<tr>
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</tr>
<tr>
<td>NUCLEAR MEDICINE</td>
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<tr>
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<td>1%</td>
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</tr>
<tr>
<td>NURSE PRACTITIONER</td>
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<tr>
<td>OBSTETRICS/GYNECOLOGY</td>
<td>$658</td>
<td>0%</td>
<td>0%</td>
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<td>-1%</td>
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<tr>
<td>OPHTHALMOLOGY</td>
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<td>0%</td>
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<tr>
<td>OPTOMETRY</td>
<td>$1,259</td>
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<td>0%</td>
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</tr>
<tr>
<td>ORAL/ MAXILLOFACIAL SURGERY</td>
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<td>0%</td>
<td>-2%</td>
<td>0%</td>
<td>-2%</td>
</tr>
<tr>
<td>ORTHOPEDIC SURGERY</td>
<td>$3,784</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>OTHER</td>
<td>$28</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
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<tr>
<td>OTOLARYNGOLOGY</td>
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</tr>
<tr>
<td>PATHOLOGY</td>
<td>$1,147</td>
<td>0%</td>
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<td>0%</td>
<td>-1%</td>
</tr>
<tr>
<td>Specialty</td>
<td>(A) Allowed Charges (mil)</td>
<td>(B) Allowed Charges (mil)</td>
<td>(C) Impact of Work RVU Changes</td>
<td>(D) Impact of PE RVU Changes</td>
<td>(E) Impact of MP RVU Changes</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>---------------------------</td>
<td>---------------------------</td>
<td>-------------------------------</td>
<td>-------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>PEDIATRICS</td>
<td>$63</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>PHYSICAL MEDICINE</td>
<td>$1,105</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>PHYSICAL/OCCUPATIONAL THERAPY</td>
<td>$3,780</td>
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<td>1%</td>
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<td>1%</td>
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<td>PHYSICIAN ASSISTANT</td>
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<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>PLASTIC SURGERY</td>
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<td>0%</td>
<td>0%</td>
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<td>0%</td>
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<td>PODIATRY</td>
<td>$1,973</td>
<td>0%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>PORTABLE X-RAY SUPPLIER</td>
<td>$100</td>
<td>0%</td>
<td>-1%</td>
<td>0%</td>
<td>-1%</td>
</tr>
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<td>PSYCHIATRY</td>
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<td>0%</td>
<td>1%</td>
<td>0%</td>
<td>1%</td>
</tr>
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<td>PULMONARY DISEASE</td>
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<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS</td>
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<td>1%</td>
<td>1%</td>
<td>1%</td>
</tr>
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<td>0%</td>
</tr>
<tr>
<td>THORACIC SURGERY</td>
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<td>-1%</td>
<td>-1%</td>
</tr>
<tr>
<td>UROLOGY</td>
<td>$1,772</td>
<td>0%</td>
<td>-1%</td>
<td>0%</td>
<td>-1%</td>
</tr>
<tr>
<td>VASCULAR SURGERY</td>
<td>$1,115</td>
<td>0%</td>
<td>-1%</td>
<td>0%</td>
<td>-2%</td>
</tr>
</tbody>
</table>

** Column F may not equal the sum of columns C, D, and E due to rounding.

2. CY 2018 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the final RVU changes are generally related to the changes to RVUs for specific services resulting from the Misvalued Code Initiative, including finalized RVUs for new and revised codes. The estimated impacts for some specialties, including behavioral health specialists, physical and occupational therapists, and radiation oncology, reflect increases relative to other physician specialties. These increases can largely be attributed to proposed increases in value for particular services following the American Medical Association Relative Value Update Committee and CMS review, the proposed change in allocation of indirect practice expense RVUs for office-based, face-to-face behavioral health services, and proposed changes based on updated professional liability premium data.
The estimated impacts for several specialties, including diagnostic testing facilities, allergy/immunology, otolaryngology, oral/maxillofacial surgery, and independent laboratories, reflect decreases in payments relative to payment to other physician specialties as a result of proposed revaluation of individual procedures reviewed by the American Medical Association Relative Value Update Committee and CMS, proposed changes based on updated professional liability premium data, proposed decreases in relative payment as a result of proposed updates to prices for particular medical supplies, and continued implementation of previously finalized code-level reductions that are being phased-in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the Clinical Laboratory Fee Schedule. As a result, the estimated 2 percent reduction for CY 2018 is only applicable to approximately 17 percent of the Medicare payment to these entities.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table, including comments received in response to the proposed rates. We remind stakeholders that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentages in the table are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. They are therefore averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

b. Impact
Column F of Table 40 displays the estimated CY 2018 impact on total allowed charges, by specialty, of all the RVU changes. A table shows the estimated impact on total payments for selected high volume procedures of all of the changes is available under “downloads” on the CY 2018 PFS proposed rule website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/. We selected these procedures for sake of illustration from among the most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.

D. Effect of Changes in Telehealth List

As discussed in section II.D. of this proposed rule, we are proposing to add several new codes to the list of Medicare telehealth services. Although we expect these changes to have the potential to increase access to care in rural areas, based on recent telehealth utilization of services already on the list, including services similar to the proposed additions, we estimate no significant impact on PFS expenditures from the proposed additions. For example, for services already on the list, they are furnished via telehealth, on average, less than 0.1 percent of the time they are reported overall.

E: Effect of Changes to Payment to Provider-Based Departments (PBDs) of Hospitals Paid under the PFS

As discussed in section II.G of this proposed rule, for CY 2018, we are proposing a PFS Relativity Adjuster of 25 percent, meaning that nonexcepted items and services furnished by nonexcepted PBDs would be paid under the PFS at a rate that is 25 percent of the OPPS rate. We
estimate that this change will result in total Medicare Part B savings of $25 million for CY 2018 relative to maintaining the CY 2017 PFS Relativity Adjuster for CY 2018.

F. Other Provisions of the Proposed Regulation

1. New Care Coordination Services and Payment for RHCs and FQHCs

As discussed in section III.A of this proposed rule, we are proposing the establishment of two new G codes for use by RHCs and FQHCs. The first new G code would be a General Care Management code for RHCs and FQHCs with the payment amount set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes. The second new G code for RHCs and FQHCs would be a Psychiatric CoCM code with the payment amount set at the average of the 2 national non-facility PFS payment rates for psychiatric CoCM services. The payment rate for each code would be updated annually, based on the national non-facility PFS payment rates for each code contained in the G code.

The proposed methodology for payment of care coordination services is consistent with the RHC and FQHC payment principles of not paying for services based on time increments. It does not create additional reporting burden and is expected to promote beneficiary access to comprehensive care management services furnished by RHCs and FQHCs.

Establishment of the RHC and FQHC General Care Management code, which includes all levels of CCM and general BHI services, is projected to increase Medicare spending by $600,000 in CY 2018 and by $7.4 million over 10 years. This estimate is based on the proposed per service allowed charge increase (from approximately $42.71 to $61.37) applied to historical 2016 CCM and BHI volume in RHCs and FQHCs. This volume was adjusted with an assumed 10 percent behavioral volume increase to reflect the increase in allowed charges per service.
Establishment of the RHC and FQHC Psychiatric CoCM code, which includes all levels of psychiatric CoCM services, is projected to increase Medicare spending by approximately $100,000 in CY2018 and $3.7 million over 10 years. Because psychiatric CoCM is not billable currently by RHCs or FQHCs and is also new to practitioners billing under the PFS, this estimate is based on first quarter 2017 PFS psychiatric CoCM claims of 0.03 percent of psychiatric E/M visits, adjusted to an ultimate average rate of 0.16 percent based on the pattern of increase in CCM services in the PFS found in the first two years of implementation. This rate was then applied to the number of 2016 RHC and FQHC mental health visits to get an estimate of CoCM volume, and then projected forward on a per-capita basis. PFS price updates were applied to the initial approximate $135 psychiatric CoCM payment amount to project future costs.

The combined increase in Medicare spending for both new G codes is estimated to be approximately $600,000 in 2018, and approximately $11.1 million over 10 years. While these services are expected to increase quality and improve efficiency over time, the programs are still new and the data is not available yet to demonstrate any cost savings. Therefore, no healthcare cost reductions were assumed as a result of increased care management.

**TABLE 42: Calendar Years 2018-2027 Projected Spending Impact of New General Care Management and Psychiatric CoCM Codes for RHCs and FQHCs (Millions)**

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>General Care Management</td>
<td>0.6</td>
<td>0.7</td>
<td>0.7</td>
<td>0.7</td>
<td>0.8</td>
<td>0.8</td>
<td>0.8</td>
<td>0.8</td>
<td>0.8</td>
<td>0.8</td>
<td>7.4</td>
</tr>
<tr>
<td>Psychiatric CoCM</td>
<td>0.1</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>3.7</td>
</tr>
<tr>
<td>Total</td>
<td>0.8</td>
<td>1.0</td>
<td>1.1</td>
<td>1.1</td>
<td>1.1</td>
<td>1.1</td>
<td>1.2</td>
<td>1.2</td>
<td>1.2</td>
<td>1.3</td>
<td>11.1</td>
</tr>
</tbody>
</table>

*Figures may not sum to totals due to rounding.*
As discussed in section III.A. of this proposed rule, we considered 3 other options (for example, allowing any of the 7 codes to be separately added to a claim, bundling all 7 codes into one G code, and developing 3 separate G codes – one each for CCM, BHI, and CoCM services). We estimate that there would be no significant difference in the costs among the options because all of the options considered include the same services paid at the same rate and no data is available to estimate a different rate of billing for each code.

2. Payment for DME Infusion Drugs

As discussed in section III.B. of this proposed rule, we proposed to conform the regulation text at §414.904(e)(2) to section 5004 of the Cures Act, which transitioned payment for DME infusion drugs from AWP-based pricing to the ASP-pricing methodology on January 1, 2017. Table 43 shows the effect of changes in drug payments to DME suppliers. We estimate adoption of the ASP+6 pricing methodology will result in total Medicare Part B savings ranging over the 10-year period from $40 million in FY 2017 to $110 million in FY 2026 with a 10-year total Medicare Part B savings of $960 million.

<table>
<thead>
<tr>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefits</td>
<td>(50)</td>
<td>(110)</td>
<td>(130)</td>
<td>(130)</td>
<td>(130)</td>
<td>(130)</td>
<td>(150)</td>
<td>(150)</td>
<td>(150)</td>
<td>(150)</td>
<td>(550)</td>
<td>(1,280)</td>
</tr>
<tr>
<td>Premium Offset</td>
<td>10</td>
<td>30</td>
<td>30</td>
<td>30</td>
<td>30</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>130</td>
<td>320</td>
</tr>
<tr>
<td>Total Part B</td>
<td>(40)</td>
<td>(80)</td>
<td>(100)</td>
<td>(100)</td>
<td>(100)</td>
<td>(100)</td>
<td>(110)</td>
<td>(110)</td>
<td>(110)</td>
<td>(110)</td>
<td>(420)</td>
<td>(960)</td>
</tr>
</tbody>
</table>

3. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

We are proposing and requesting public comment on the appropriate use criteria (AUC) consulting and reporting requirements and the effective date on which these requirements will begin. We are also proposing modifications to the significant hardship exception to better align
these exceptions under the AUC program with those under existing quality programs. In the COI section of this document, we have estimated the proposed consulting requirement to result in an annual burden of 1,425,000 hours at a cost of $275,139,000. Under these proposals, claims for advanced diagnostic imaging services would not be denied in CY 2018, and thus, these proposals would not impact CY 2018 physician payments under the PFS. The Congressional Budget Office estimates that section 218 of the PAMA would save approximately 200 million dollars over 10 years from FY 2014 through 2024, which could be the result of identification of outlier ordering professionals. Because we have not yet proposed a mechanism or calculation for outlier ordering professional identification and prior authorization, we are unable to quantify that impact at this time. We will provide an impact statement when applicable in future rulemaking.


a. Burden Estimate for PQRS Reporting

We previously discussed the burden estimate for PQRS regarding the program year 2016 reporting criteria, which applies to the 2018 payment adjustment in the CY 2016 PFS final rule (see 80 FR 71362 through 71367). The burden estimates for reporting that data have not changed since these data for program year 2016 PQRS have already been reported; therefore, there are no added burden estimates for the proposed policy change in this rule in section III.F.

b. Burden Savings Estimated Based on PQRS Measures Reduction Proposed Policy

Amending the policy to reduce the amount of measures needed to satisfactorily report to avoid the 2018 payment adjustment from 9 measures across 3 NQS domains to 6 measures (see section III.F. of this proposed rule) would increase the amount of satisfactory reporters for the 2016 reporting period, which would decrease those subject to the 2018 payment adjustment. Using data from the 2015 reporting period as the basis for our estimates, there were roughly
525,000 eligible professionals who failed the PQRS reporting requirements for the 2015 reporting period and received a downward payment adjustment in 2017 (see https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_PQRS_Experience_Report.pdf). We estimate that, based on 2015 results, approximately 4.5 percent of EPs that received a downward payment adjustment would be found successful and therefore would avoid the payment penalty. This equates to an estimated 23,625 EPs that would no longer be subject to the 2018 payment adjustment based on PQRS data for the 2015 reporting period.

Based on the estimated average payment adjustment of $937.02 in program year 2015, which was negative 2 percent based on 2015 PFS charges, an estimated ($937.02 x 23,625 = $22,137,097.50) would be the amount EPs would receive as a result of not being subject to the 2018 payment adjustment due to the proposed measure reduction policy in this rule for PQRS program year 2016, which applies to the 2018 payment adjustment.

5. Medicare Shared Savings Program

We are proposing certain modifications to our rules regarding ACO assignment and financial calculations, quality measures and quality validation audits, TIN overlaps, and application requirements. Specifically we are proposing: (1) Modifications to how services furnished by FQHCs and RHCs are used for purposes of beneficiary assignment to an ACO as a result of the 21st Century Cures Act, including reducing reporting burden for ACOs that include FQHCs and RHCs; (2) modifications to the assignment methodology to include new chronic care management and behavioral health integration codes in our definition of primary care services; (3) a policy to improve the quality validation audit process and, absent unusual circumstances, to use the results to proportionally modify an ACO’s overall quality score; (4) a policy to address
substantive changes to quality measures made under the Quality Payment Program; (5) revisions to our application requirements to reduce burden for ACO applicants seeking to participate in the Shared Savings Program and for ACOs applying to use the SNF 3-Day Rule Waiver; (6) changes to our program rules to address compliance with our ACO participant TIN overlap policies, specifically, to address situations in which overlapping ACO participant TINs begin billing for services that are used in beneficiary assignment during a benchmark or performance year; and (7) a policy to use final beneficiary identifiable non-claims based payments in establishing benchmarks and performing financial reconciliation.

Each of these proposed policies is generally expected to have a minimal impact on affected ACOs. We do not anticipate any overall impact for these proposed policies because potential individual ACO impacts are more likely to offset one another rather than build to a substantial total in terms of costs or savings.

6. Value-Based Payment Modifier and the Physician Feedback Program

Section 1848(p) of the Act requires that we establish a value-based payment modifier (VM) and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015, and to all physicians and groups of physicians by January 1, 2017. Section 1848(p)(4)(C) of the Act requires the VM to be budget neutral. Budget-neutrality means that, in aggregate, the increased payments to high performing physicians and groups equal the reduced payments to low performing physicians and groups, as well as those physicians and groups that failed to meet the criteria to avoid the PQRS payment adjustment as a group or as individuals.

In the CY 2016 PFS final rule with comment period (80 FR 71277 and 71279), we established that, beginning with the CY 2018 payment adjustment period, the VM will apply to
nonphysician EPs who are physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified registered nurse anesthetists (CRNAs) in groups with 2 or more EPs and to PAs, NPs, CNSs, and CRNAs who are solo practitioners.

In CY 2018, the VM will be waived for groups and solo practitioners, as identified by their TIN, if at least one EP who billed for Medicare PFS items and services under the TIN during 2016 participated in the Pioneer ACO Model, the Comprehensive Primary Care initiative, Next Generation ACO Model, the Oncology Care Model, and the Comprehensive ESRD Care Initiative in 2016 (80 FR 71286 through 71288).

In the CY 2016 PFS final rule with comment period (80 FR 71280), we adopted a two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners. For the purposes of the CY 2018 VM, Category 1 represents those groups and solo practitioners subject to the VM who met the criteria to avoid the 2018 PQRS payment adjustment (a) as a group practice participating in the PQRS GPRO, (b) groups that have at least 50 percent of the group’s EPs meet the criteria to avoid the 2018 PQRS payment adjustment for CY 2018 as individuals, (c) solo practitioners that meet the criteria to avoid the CY 2018 PQRS payment adjustment as individuals, and (d) groups and solo practitioners that participated in a Shared Savings Program ACO, if the ACO in which they participate successfully reports quality data as required by the Shared Savings Program. Category 2 represents those groups and solo practitioners that are subject to the CY 2018 VM payment adjustment and do not fall within Category 1.

In section III.I. of this proposed rule, we are proposing to reduce the CY 2018 VM payment adjustment amount for groups and solo practitioners in Category 2. We proposed to reduce the automatic payment adjustment from -4.0 percent to -2.0 percent for Physicians, PAs,
NPs, CNSs, and CRNAs in groups with 10 or more EPs and at least one physician and from -2.0 percent to -1.0 percent for Physicians, PAs, NPs, CNSs, and CRNAs in groups of 2 or more EPs, PAs, NPs, CNSs, and CRNAs in groups comprised solely of non-physician EPs and physician and non-physician solo practitioners.

Additionally, in section III.I. in this proposed rule, we are proposing that, under quality-tiering, which is the methodology for evaluating performance on quality and cost measures for the VM, there will be no downward adjustments for groups or solo practitioners in Category 1 for the VM for CY 2018. We are also proposing to reduce the maximum upward adjustment under the quality-tiering methodology in CY 2018 for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs and at least one physician that are Category 1 from four times an adjustment factor (+4.0x) to two times an adjustment factor (+2.0x) for those classified as high quality/low cost and from two times an adjustment factor (+2.0x) to one times an adjustment factor (+1.0x) for those classified as either average quality/low cost or high quality/average cost. This proposal aligns the upward adjustment for groups of 10 or more EPs with those previously finalized for smaller groups and solo practitioners, as well as groups comprised solely of non-physician EPs and provides a smoother transition to MIPS by bringing the incentives in line with those in the first year of the MIPS.

Under the quality-tiering methodology, each group and solo practitioner’s quality and cost composites will continue to be classified into high, average, and low categories depending upon whether the composites are at least one standard deviation above or below the mean and statistically different from the mean. We will compare their quality of care composite classification with the cost composite classification to determine their VM adjustment for the CY 2018 payment adjustment period according to the amounts in Table 44.
TABLE 44: Proposed CY 2018 VM Amounts under the Quality-Tiering Approach for Physicians, Pas, NPs, CNSs, and CRNAs who are in Groups or Solo Practitioners

<table>
<thead>
<tr>
<th>Cost/Quality</th>
<th>Low quality</th>
<th>Average quality</th>
<th>High quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low cost</td>
<td>+0.0%</td>
<td>+1.0x*</td>
<td>+2.0x*</td>
</tr>
<tr>
<td>Average cost</td>
<td>+0.0%</td>
<td>+0.0%</td>
<td>+1.0x*</td>
</tr>
<tr>
<td>High cost</td>
<td>+0.0%</td>
<td>+0.0%</td>
<td>+0.0%</td>
</tr>
</tbody>
</table>

*Groups and solo practitioners eligible for an additional +1.0x if reporting measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where ‘x’ represents the upward payment adjustment factor.

Under the quality-tiering methodology, for groups and solo practitioners that participated in a Shared Savings ACO that successfully reports quality data for CY 2016, the cost composite will be classified as “Average” and the quality of care composite will continue to be based on ACO-level quality measures. We will compare their quality of care composite classification with the “Average” cost composite classification to determine their VM adjustment for the CY 2018 payment adjustment period. For groups and solo practitioners that participate in a Shared Savings Program ACO that did not successfully report quality data for CY 2016 and are Category 1 as a result of quality data reported to the PQRS outside of the ACO, the quality and cost composites will continue to be classified as “Average”.

To ensure budget neutrality, we first aggregate the automatic downward payment adjustments of -1.0 percent or -2.0 percent for groups and solo practitioners subject to the VM that fall within Category 2. Using the aggregate downward payment adjustment amount, we then calculate the upward payment adjustment factor (x). Additionally, as we have done when calculating the upward payment adjustment factor for the 2017 VM, we will also incorporate adjustments made for estimated changes in physician behavior (that is, changes in the volume and/or intensity of services delivered and shifting of services to TINs that receive higher VM
adjustments) and estimated impact of pending PQRS and VM informal reviews. These calculations will be done after the performance period has ended and announced around the start of the payment adjustment year after the informal review period ends.

At the time of this proposed rule, we have not completed the analysis of the impact of the VM in CY 2018 on physicians and non-physicians in groups of 2 or more EPs and physician and non-physician solo practitioners based on performance in 2016. However, preliminary estimates indicate that the implementation of the proposed policies discussed above, would reduce the adjustment factor to below 10 percent. In the CY 2018 PFS final rule, we will present the number of groups and solo practitioners that will be subject to the VM in CY 2018.

7. MACRA Patient relationship Categories and Codes

We are soliciting comments on these HCPCS codes. Our intention is to collect the codes beginning January 2018, and our plan not to tie the collection of the codes with payment until we are sure clinicians have gained ample experience and education in using these modifiers. Therefore, there is no impact to CY 2018 physician payments under the PFS. There may be a burden associated with clinicians and their administrative staff having to learn which codes to use and how to submit them properly.

8. Effects of Proposals Relating to the Medicare Diabetes Prevention Program Expanded Model

In section III.K of the preamble of this proposed rule, we discuss our proposals to further implement the MDPP expanded model under the authority of section 1115A of the Act, which authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid and CHIP beneficiaries. The MDPP expanded model was established in the November 15, 2016 MDPP final rule as an additional preventive service with a model effective
date of January 1, 2018. Many of the policies for the MDPP expanded model were deferred to future rulemaking and, therefore, are being proposed in this rule. On March 14, 2016, the Office of the Actuary (OACT) published a certification memorandum setting out the conditions for expansion of the Medicare Diabetes Prevention Program (MDPP). Prior to its implementation, OACT is required to review the parameters of the MDPP expansion and provide an updated certification. This regulatory impact assessment is not an updated certification; rather, it is based on estimates of the proposed rule.

Diabetes affects more than 25 percent of Americans aged 65 or older and its prevalence is projected to increase approximately two-fold for all U.S. adults (ages 18-79) by 2050 if current trends continue. Furthermore, the risk of progression to type 2 diabetes in an individual with pre-diabetes is 5-10 percent per year, or 5-20 times higher than in individuals with normal blood glucose. We estimate that Medicare spent $42 billion more in the single year of 2016 on fee-for-service, non-dual eligible, over age 65 beneficiaries with diabetes and related comorbidities than it would have spent if those beneficiaries did not have diabetes, including $20 billion more for Part A, $17 billion more for Part B, and $5 billion more for Part D. The goal of the MDPP expanded model is to reduce the incidence rate of type 2 diabetes among Medicare beneficiaries with prediabetes through a structured behavioral change program where the primary outcome is

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weight loss. Weight loss is a key indicator of success among persons enrolled in a Diabetes Prevention Program due to the strong association between weight loss and reduction in the risk of type 2 diabetes. In reducing the incidence rate of type 2 diabetes we expect to reduce Medicare spending while improving quality of care for eligible beneficiaries. In this proposed rule, we are proposing a value-based payment structure for the MDPP Expanded Model. Instead of traditional fee-for-service payment, our proposed payment structure shifts risk from Medicare to the rendering supplier by making payments for MDPP services to MDPP suppliers based on the achievement of performance goals.

a. Anticipated Effects

(1) Effects on Beneficiaries

The MDPP expanded model is expected to have a positive impact on beneficiaries’ health that will generally lead to reduced beneficiary spending on Part A, Part B, and Part D health care services over time due to a reduced need for Part A, Part B, and Part D services. As a new preventive service, the MDPP services are available to eligible Medicare beneficiaries without cost-sharing. The CDC estimates that approximately 50 percent of adults aged 65 and over living in the United States have prediabetes and that awareness of the condition among those who have it is relatively low—approximately 30 percent for the general population. Therefore, we anticipate that up to 7 million Medicare beneficiaries who are aware of their prediabetes would be eligible for the MDPP services at the start of the MDPP expanded model. This estimate does not take into account any increased beneficiary awareness of their prediabetes due to the availability of MDPP services. We also expect there to be pent-up demand, with the number of beneficiaries utilizing the MDPP services greater in the initial few years (roughly

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65,000 to 110,000 per year) but then leveling off afterwards (to a base demand of roughly 50,000 participants per year).

To arrive at our participation estimate we developed projections for pent-up demand and ongoing demand. To develop the projection for pent-up demand we first analyzed data from the CDC National Diabetes Prevention Recognition Program (DPRP). Specifically, we analyzed State-by-State DPRP in-person utilization for ages 65 or older in 2015. Because the Health Care Innovation Award (HCIA) MDPP model test was still serving beneficiaries during this period, and the HCIA DPP suppliers are also part of the DPRP, we used its enrollment data to inform what Medicare beneficiary participation may look like when Medicare pays for MDPP. Given that HCIA participation seemed to drive most of the DPRP participation in an HCIA supplier’s region, we determined that a well-defined HCIA region would be a reasonable proxy for the rest of the nation. We found the state with the highest HCIA saturation, and calculated the percentage of fee for service beneficiaries that received services from a DPRP DPP. This percentage was applied to all fee for service beneficiaries nationwide in order to get a national pent-up demand estimate. We added this pent-up demand to a stable level of demand based on the number of new beneficiaries utilizing the obesity management benefit each year. Given the limited nationwide Medicare DPP participation data, there is a great amount of uncertainty in these estimates.

We believe that the eligibility criteria for continued participation in the set of MDPP services incentivizes beneficiaries to lose 5-percent body weight from baseline. Beneficiaries are incentivized to lose weight because continued eligibility for the services benefit after the first 12 months is contingent upon achieving 5-percent weight loss and the set of MDPP services is a once per lifetime set of services. In addition to prevention of type 2 diabetes, we believe participating beneficiaries would likely receive other possible health benefits including
prevention of obesity for those who are overweight upon receiving MDPP services, prevention of sleep apnoea, and reduced risk for heart disease, coronary artery disease and stroke.37 Furthermore, we believe the MDPP expanded model could improve mental health and wellbeing by affording beneficiaries social interaction with their peers during sessions and could lead to reduced social isolation. 38 The prevention of type 2 diabetes and these other potential health benefits of MDPP services may result in reduced beneficiary expenditures for health care services over time as services will not be needed to treat health conditions that are avoided.

(2) Effects on the Market

Currently, more than 1,200 organizations nationally are providing DPP services with some level of recognition through the CDC. Service delivery is primarily to individuals with private or employer-sponsored insurance, as well as some Medicare Advantage plans. The

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majority of existing DPP organizations are not enrolled in the Medicare program. We anticipate that the addition of MDPP services as new preventive services in Medicare would result in growth in the market, including growth in the number of individuals served per year by existing DPP suppliers, as well as the introduction of new suppliers into the market. There are burdens associated with obtaining CDC recognition and enrolling into Medicare as an MDPP supplier. There is also burden associated with submitting claims to Medicare for payment. Below we have provided an estimate of the financial burden to suppliers.

(3) Burden Related to Information Collection Requirements

(a) Wage Estimates

To derive average costs for use throughout the subsequent sections, we used data from the U.S. Bureau of Labor Statistics’ May 2015 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm). Table 45 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

<table>
<thead>
<tr>
<th>Occupation Title</th>
<th>Occupation Code</th>
<th>Mean hourly wage ($/hr)</th>
<th>Fringe benefits and Overhead ($/hr)</th>
<th>Adjusted hourly wage ($/hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical records and health information technician</td>
<td>29-2071</td>
<td>19.93</td>
<td>19.93</td>
<td>39.84</td>
</tr>
<tr>
<td>Office and administrative support worker</td>
<td>43-9000</td>
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<td>16.31</td>
<td>32.62</td>
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<tr>
<td>Billing and posting Clerk</td>
<td>43-3011</td>
<td>$18.09</td>
<td>$18.09</td>
<td>$36.18</td>
</tr>
</tbody>
</table>

(b) Interim Preliminary Recognition

Our proposals under proposed §424.205 would provide that an entity is eligible to enroll in Medicare as an MDPP supplier if it has MDPP interim preliminary recognition, as determined
by CMS. In order to receive MDPP interim preliminary recognition, we are proposing that the entity must have pending CDC recognition and must submit a full 12 months of data on at least one completed cohort of participants to CDC. In order to receive pending recognition from CDC, organizations are required to submit an application for recognition to CDC and agree to CDC’s curriculum, duration and intensity requirements. CMMI plans to engage CDC’s services to assist CMMI in administering its interim preliminary recognition standard, if finalized. CMMI would make the final determination of which entities qualify to receive interim preliminary recognition.

The burden associated with the preceding requirements is the time for MDPP staff to: submit an application for pending recognition to CDC and then collect and submit a full 12 months of data (including session attendance, body weight documentation, physical activity minutes documentation, and weight loss achieved) on at least one completed cohort of participants to CDC for the purposes of being evaluated for interim preliminary recognition.

We estimate that it will take a medical records and health information technician 12 hours, at $38.88/hour to collect and report these data for one cohort of participants, and an office or administrative worker 1 hour, at $31.54/hour, to complete the CDC application for pending recognition. The estimated cost per supplier to achieve interim preliminary recognition is $498.10.

(c) Supplier Standards

Our proposals under proposed revised §424.59 (proposed in this rule to be redesignated at §424.205) would require that an MDPP supplier must certify in its enrollment application, which is a new Medicare enrollment application that we are creating specific to MDPP suppliers, and that it meets a set of standards. As this new enrollment application is being created specifically
for the MDPP expanded model, we have determined that it is exempt from the Paperwork Reduction Act in accordance with section 1115A(d)(3) of the Act. We estimate that it will take an office or administrative support worker 3 hours, at $31.54/hour, to complete the MDPP supplier enrollment application using the internet-based Provider Enrollment, Chain and Ownership System (PECOS). In general, provider enrollment fees for Medicare are $560 in 2017. We also note that CMS provides hardship exceptions to the application fee with a written request that describes the need for the hardship exception. CMS determines such exceptions on a case-by-case basis. The estimated cost to complete the MDPP supplier enrollment application, without a hardship exception, is $843.86. If a provider is granted a hardship exception from the enrollment fee, then the estimated cost to complete the enrollment process is $283.86.

We also note that access to the HIPAA Eligibility Transaction System (HETS), which a supplier could use to check factors of eligibility for the MDPP services, including the beneficiary’s Part B eligibility and whether the beneficiary has received coverage for end-stage renal disease (ESRD) is free to suppliers, as long as they are active Medicare fee-for-service providers or suppliers in PECOS.

Suppliers also would be required to maintain documentation of all beneficiary contact regarding complaints or questions, as specified in proposed §424.205(d)(11), and maintain and submit to CMS a crosswalk file which indicates how participant identifications for the purposes of CDC performance data correspond to Medicare Beneficiary Identifiers (that is, beneficiary health insurance claims numbers) for each beneficiary receiving MDPP services. We estimate that creating and maintaining documentation of beneficiary contact regarding complaints or questions will take an office or administrative support worker 1 hour, at $31.54/hour, per complaint or question request to create and maintain documentation of the request. We have no
way to estimate how many complaints or questions MDPP suppliers will receive from beneficiaries, and we expect that may differ based on many factors, so have not included an overall cost in this burden estimate. Further, we estimate that it will take an office and administrative support worker approximately 4 hours, at $31.54/hour, to create and submit the crosswalk file for a cohort of 100 beneficiaries participating in the MDPP services, for a total cost of $126.16 per cohort of 100 beneficiaries. The crosswalk is proposed to be submitted quarterly. Therefore, for a year of delivering the set of MDPP services the estimated total cost to create and submit the crosswalk file would be $504.64 per cohort of 100 beneficiaries. We believe the incremental costs to meet this requirement would decrease with the addition of beneficiaries to a cohort, because the work and time to establish the file and submit it would be the same for a cohort of 100 and a cohort of 1000. What would be different is the collection of the information from the beneficiaries, and the addition of these data points to the file. We estimate that, for every additional 100 beneficiaries added to the file, the office and administrative support worker would add 1 hour, at $31.54/hour. We estimate the total incremental cost over 1 year for each additional 100 beneficiaries above the cohort of 100 beneficiaries is $126.16.

Our proposals under proposed §424.205 also would require that suppliers meet a set of standards that includes maintaining a physical facility on an appropriate site and maintain a primary business telephone that is operating at the appropriate site. Because we have no way to estimate how many beneficiaries each MDPP supplier may provide the set of MDPP services to, and we expect this will differ based on many factors, including but not limited to the size of the supplier, the number of coaches the supplier employs, the physical space the supplier uses to furnish MDPP services, and the supplier’s geographic location, we have not included an overall
cost for these requirements in this burden estimate.

(d) Payment for MDPP Services

Our proposals under proposed §414.84 specify the proposed payments MDPP suppliers may be eligible to receive for furnishing MDPP services and meeting performance targets related to beneficiary weight loss and/or attendance. MDPP suppliers would be paid by CMS by submitting claims for MDPP beneficiaries using claim form CMS-1500 (https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf), and as a condition for payment, claims submitted by MDPP suppliers must be for services furnished to eligible beneficiaries in accordance with §414.84(b) and (c). Our proposal under proposed §424.205 would require MDPP suppliers to include an attestation that the MDPP beneficiary for which it is submitting a claim has met the performance goals laid out in proposed §424.205. Section 424.205 also proposes to require MDPP suppliers to report the NPI of the coach on MDPP claims as a program integrity safeguard. To meet these requirements for submitting claims, we estimate that it would take a billing and posting clerk 10 minutes per beneficiary to fill out the claim form and submit it to CMS at $33.70/hour. Based on this time and wage, we estimate the total cost per beneficiary per claim to be $5.62. As mentioned previously, we have no way to estimate how many beneficiaries to whom each MDPP supplier may furnish MDPP services. Therefore, we have not included an estimate of the overall cost of submitting claims in the burden estimate.

(4) Effects on the Medicare Program

(a) Estimated 10-Year Impact of MDPP

The set of MDPP services is an optional set of services for beneficiaries who meet the eligibility requirements described elsewhere in the proposed rule. MDPP services will be
furnished by a new provider type in Medicare. The CDC recognizes DPPs nationwide; these programs effectively deliver lifestyle-changing services that reduce the incidence of type 2 diabetes. The number of CDC-recognized DPPs is growing rapidly, increasing by nearly 90 percent from September 2015 to March 2017. The historical participation rate suggests that the vast majority of these providers are not serving a significant volume of new participants, aside from those served in the DPP model test.

This estimate is based on the initial methodology used for the estimate of the MDPP expanded model as set out in the certification memorandum, but with differences in several program features including the payment parameters. It also includes the impact of improved longevity among those who participate in the MDPP expanded model. This cost of improved longevity was ignored for certification purposes, as noted in that memorandum.

The model is dependent on the number of eligible participants, the annual take-up rate, and the savings per participant, all of which are uncertain. The methodology determines gross savings as the result of an assumed reduction in the number of beneficiaries transitioning from prediabetes to diabetes and a marginal cost difference between the individuals with diabetes and those that are prediabetic. The Office of the Actuary assumed that the initial savings per beneficiary for avoiding diabetes is $3,000 per year. The progression rate from prediabetes to diabetes absent the intervention is expected to be roughly 5 percent per year. Based on observed results, we assume that the set of MDPP services will reduce the progression rate among those receiving the services by 50 percent in the first year and that the reduction will be 5 percent less in each subsequent year until leveling off at a rate of 10 percent. The program costs in this estimate include payments to MDPP suppliers in the initial year of the MDPP services period and in the 2 maintenance years. Based on the results of the DPP model test regarding the
number of sessions attended and the weight loss achieved, we estimate the average expected Medicare payment per participant to be approximately $320 in the first year and $75 in each of the following 2 years. Overall, the payments under the expanded model would occur in the first 3 years following the beneficiary’s first MDPP services, but the expected reduction in medical costs would occur over a long period following the intervention. For the leading cohort of 2018, we would expect savings in excess of costs by 2019 (the second year), with cumulative savings by 2022 (after 4 years). Yearly net savings reduce slightly each subsequent year but do not result in a cost to Medicare during the 10-year projection window.

Table 46 shows the 10-year impact of the MDPP expanded model, net of payments to MDPP providers but gross of any other model costs, based on our expected enrollment per year. The 10-year impact is a savings to Medicare of $186 million. The estimate is expected to cross into a cumulative savings to Medicare in the sixth year of the MDPP expanded model.

TABLE 46: Estimated 10-Year Impact of MDPP on Net Claims Costs, Payments to Providers, and Net Savings for CYs 2018 through 2027
(In millions, negative values indicate savings)

<table>
<thead>
<tr>
<th>Year</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>2024</th>
<th>2025</th>
<th>2026</th>
<th>2027</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Claim Costs</td>
<td>-$5</td>
<td>-$16</td>
<td>-$29</td>
<td>-$41</td>
<td>-$52</td>
<td>-$60</td>
<td>-$66</td>
<td>-$70</td>
<td>-$72</td>
<td>-$72</td>
<td>-$484</td>
</tr>
<tr>
<td>Provider Payments</td>
<td>$21</td>
<td>$41</td>
<td>$40</td>
<td>$31</td>
<td>$28</td>
<td>$26</td>
<td>$27</td>
<td>$28</td>
<td>$28</td>
<td>$29</td>
<td>$298</td>
</tr>
<tr>
<td>Net Savings</td>
<td>$16</td>
<td>$25</td>
<td>$11</td>
<td>-$10</td>
<td>-$25</td>
<td>-$34</td>
<td>-$40</td>
<td>-$43</td>
<td>-$44</td>
<td>-$43</td>
<td>-$186</td>
</tr>
<tr>
<td>Cumulative Net Savings</td>
<td>$16</td>
<td>$41</td>
<td>$52</td>
<td>$42</td>
<td>$17</td>
<td>-$17</td>
<td>-$56</td>
<td>-$99</td>
<td>-$143</td>
<td>-$186</td>
<td></td>
</tr>
</tbody>
</table>

(b) Sensitivity Testing

MDPP is a new Medicare expanded model that was tested in the DPP model test using a small percentage of the population. As a result, the estimated impact from the expanded MDPP model is very uncertain. In particular, it is unknown how many beneficiaries will be interested in participating in MDPP and how quickly MDPP suppliers available will be able to serve those individuals. To understand how various participation scenarios would affect the financial results,
we have prepared the estimates under two other participation scenarios. The first shows the results if half of the beneficiaries shown in the best estimate participate, and the second uses twice as many beneficiaries. The details are shown in Tables 47 and 48.

**TABLE 47: Scenario Test of MDPP 10-Year Impact of Half the Expected Participants on Net Claims Costs, Payments to Providers, and Net Savings for CYs 2018 through 2027**

<table>
<thead>
<tr>
<th>Year</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>2024</th>
<th>2025</th>
<th>2026</th>
<th>2027</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider Payments</td>
<td>$10</td>
<td>$20</td>
<td>$20</td>
<td>$16</td>
<td>$14</td>
<td>$13</td>
<td>$14</td>
<td>$14</td>
<td>$14</td>
<td>$149</td>
<td></td>
</tr>
<tr>
<td>Net Savings</td>
<td>$8</td>
<td>$13</td>
<td>$5</td>
<td>-$5</td>
<td>-$12</td>
<td>-$17</td>
<td>-$20</td>
<td>-$21</td>
<td>-$22</td>
<td>-$22</td>
<td>-$93</td>
</tr>
</tbody>
</table>

**TABLE 48: Scenario Test of MDPP 10-Year Impact of Double the Expected Participants on Net Claims Costs, Payments to Providers, and Net Savings for CYs 2018 through 2027**

<table>
<thead>
<tr>
<th>Year</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>2024</th>
<th>2025</th>
<th>2026</th>
<th>2027</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Claim Costs</td>
<td>-$9</td>
<td>-$31</td>
<td>-$58</td>
<td>-$83</td>
<td>-$104</td>
<td>-$121</td>
<td>-$133</td>
<td>-$140</td>
<td>-$144</td>
<td>-$145</td>
<td>-$969</td>
</tr>
<tr>
<td>Provider Payments</td>
<td>$41</td>
<td>$82</td>
<td>$80</td>
<td>$63</td>
<td>$55</td>
<td>$52</td>
<td>$54</td>
<td>$55</td>
<td>$56</td>
<td>$58</td>
<td>$596</td>
</tr>
<tr>
<td>Net Savings</td>
<td>$32</td>
<td>$50</td>
<td>$22</td>
<td>-$20</td>
<td>-$49</td>
<td>-$68</td>
<td>-$79</td>
<td>-$85</td>
<td>-$88</td>
<td>-$87</td>
<td>-$372</td>
</tr>
</tbody>
</table>

b. Alternatives Considered for MDPP

Section III.K. of the preamble of this proposed rule includes a range of proposed policies necessary to implement the MDPP expanded model, including benefit structure, payment, supplier enrollment, and supplier standards. Throughout section III.K., we present descriptions of the relevant statutory provisions; identify those policies when discretion has been exercised in our proposals, present rationale for our proposed policies; and discuss alternative to our proposals that where considered.

We considered alternatives to the MDPP services period that would significantly impact the potential payment. Specifically, we considered limiting the MDPP to a 12-month MDPP services period without any ongoing maintenance sessions available in months 13 through 36. It is estimated that the average payment to suppliers for the maintenance years is $75 per year per
beneficiary. We also considered limiting the ongoing maintenance sessions to 12 months, culminating in a total MDPP service period of up to 2 years as opposed to up to 3 years. Either of these alternatives would reduce the total potential payment to MDPP suppliers by 52 percent or 28 percent, respectively, from a maximum of $810 for meeting all attendance and weight loss achievement goals under our proposals. We did not propose these alternatives because weight loss is difficult to achieve and can be more difficult to sustain. Our proposal to allow for up to 2 years of ongoing maintenance sessions for those beneficiaries who have achieved a minimum 5 percent weight loss from baseline during months 1 to 12 of the MDPP services period will allow for reinforcement of the lifestyle changes needed to maintain weight loss. Finally, a 3-year diabetes prevention program is supported by evidence from the NIH DPP clinical trial.

In this proposed rule, we also considered linking additional outcomes beyond attendance and weight loss to payment in the value-based payment methodology. Specifically, we considered linking hemoglobin A1c level to MDPP payments. However, we did not adopt this alternative because the MDPP expanded model is certified based on the DPP model test, which demonstrated that weight loss was associated with reductions in Medicare expenditures. Although elevated hemoglobin A1c levels were included as part of the beneficiary eligibility criteria in the DPP model test, hemoglobin A1c levels were not evaluated post-intervention in the DPP model test. Therefore, the proposed MDPP payment structure would incentivize MDPP suppliers to prioritize the achievement of beneficiary weight loss by furnishing MDPP services, providing a balance between value-based payments related to weight loss and session attendance.

In conclusion, we estimate that the 10-year impact of the MDPP expanded model, net of payments to MDPP providers but gross of any other program costs, based on our expected
enrollment per year would be a savings to Medicare of $186 million. The estimate is expected to cross into a cumulative savings to Medicare in the sixth year of the MDPP expanded model.

F. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this proposed rule, we presented the estimated impact on total allowed charges by specialty. The alternatives we considered, as discussed in the preceding preamble sections, will result in different proposed payment rates, and therefore, result in different estimates than those shown in Table 40 (CY 2018 PFS Estimated Impact on Total Allowed Charges by Specialty).

G. Impact on Beneficiaries

There are a number of changes in this proposed rule that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through revisions to the inputs used to calculate payments under the PFS, would have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

Most of the aforementioned proposed policy changes could result in a change in beneficiary liability as relates to coinsurance (which is 20 percent of the fee schedule amount, if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in our public use file Impact on Payment for Selected Procedures available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-
Payment/PhysicianFeeSched/, the CY 2017 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was $109.46, which means that in CY 2017, a beneficiary would be responsible for 20 percent of this amount, or $21.89. Based on this proposed rule, using the CY 2018 CF, the CY 2018 national payment amount in the nonfacility setting for CPT code 99203, as shown in the Impact on Payment for Selected Procedures table, is $109.77, which means that, in CY 2018, the final beneficiary coinsurance for this service would be $21.95.

H. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year’s proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year’s rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.
Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits https://www.bls.gov/oes/current/oes_nat.htm. Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is $841 (8.0 hours x $105.16). Therefore, we estimate that the total cost of reviewing this regulation is $4,981,243 ($841 x 5,943 reviewers).

I. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf), in Tables 49 and 50 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2017 to CY 2018 based on the FY 2018 President’s Budget baseline.

**TABLE 49: Accounting Statement: Classification of Estimated Expenditures**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>TRANSFERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CY 2018 Annualized Monetized Transfers</td>
<td>Estimated increase in expenditures of $0.3 billion for PFS CF update.</td>
</tr>
<tr>
<td>From Whom To Whom?</td>
<td>Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>TRANSFER</th>
</tr>
</thead>
<tbody>
<tr>
<td>CY 2018 Annualized Monetized Transfers of beneficiary cost coinsurance.</td>
<td>$0.1 billion</td>
</tr>
<tr>
<td>From Whom to Whom?</td>
<td>Federal Government to Beneficiaries.</td>
</tr>
</tbody>
</table>

**TABLE 50: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>TRANSFER</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICR Burden</td>
<td>$282 million</td>
</tr>
<tr>
<td>MDPP</td>
<td>$186 million</td>
</tr>
<tr>
<td>Regulatory Familiarization</td>
<td>$5 million</td>
</tr>
</tbody>
</table>
J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides a Regulatory Impact Analysis. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.
List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.
For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for part 405 continues to read as follows:

   Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

2. Section 405.2413 is amended by revising paragraph (a)(5) to read as follows:

§405.2413 Services and supplies incident to a physician's services.

   (a) * * *

   (5) Furnished under the direct supervision of a physician, except that services and supplies furnished incident to Transitional Care Management, General Care Management, and the Psychiatric Collaborative Care model, can be furnished under general supervision of a physician when these services or supplies are furnished by auxiliary personnel, as defined in §410.26(a)(1) of this chapter.

   * * * * *

3. Section 405.2415 is amended by revising paragraph (a)(5) to read as follows:

§405.2415 Incident to services and direct supervision.

   (a) * * *

   (5) Furnished under the direct supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, except that services and supplies furnished incident to Transitional Care Management, General Care Management, and the Psychiatric Collaborative Care model, can be furnished under general supervision of a nurse practitioner, physician assistant, or certified
nurse-midwife, when these services or supplies are furnished by auxiliary personnel, as defined in §410.26(a)(1) of this chapter.

* * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

4. The authority citation for part 410 is revised to read as follows:

   **Authority:** Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd).

5. Section 410.79 is amended by—

   a. Revising the section heading and paragraph (a);

   b. Under paragraph (b):

      i. Revising the definition of “Baseline weight”;

      ii. Removing the definition “Coach”;

      iii. Revising the definition of “Core maintenance session”;

      iv. Adding in alphabetical order a definition for “Core maintenance session interval;”

      v. Revising the definition of “Core session”;

      vi. Removing the definitions of “Maintenance of weight loss” and “Maintenance session bundle”;

      vii. Adding in alphabetical order definitions for “Make-up session” and “MDPP beneficiary”;

      viii. Removing the definitions of “MDPP core benefit” and “MDPP eligible beneficiary”;

      ix. Revising the definition of “MDPP services”;

      x. Adding in alphabetical order definitions for “MDPP services period” and “MDPP session”;


xi. Revising the definitions of “MDPP supplier” and “Medicare Diabetes Prevention Program (MDPP)”;

xii. Adding in alphabetical order a definition for “Ongoing maintenance session interval”;

xiii. Revising the definition of “Ongoing maintenance sessions”; and

xiv. Adding in alphabetical order definitions for “Set of MDPP services” and “Virtual make-up session”; and

c. Revising paragraphs (c) and (d).

The revisions and additions read as follows:

§410.79 *Medicare Diabetes Prevention Program expanded model: Conditions of coverage.*

(a) Medicare Diabetes Prevention Program (MDPP) services will be available beginning on April 1, 2018.

(b) * * *

Baseline weight means the MDPP beneficiary’s body weight recorded during that beneficiary’s first core session.

* * * * *

Core maintenance session means an MDPP service that--

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during a core maintenance session interval;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for maintenance sessions.

Core maintenance session interval means one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers an MDPP beneficiary at least one core maintenance session per month.
Core session means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during months 1 through 6 of the MDPP services period;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for core sessions.

* * * * *

Make-up session means a core session, a core maintenance session, or an ongoing maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session, core maintenance session, or ongoing maintenance session.

MDPP beneficiary means a Medicare beneficiary who meets the criteria specified in paragraph (c)(1)(i) of this section, who has initiated the MDPP services period by attending the first core session, and for whom the MDPP services period has not ended as specified in paragraph (c)(3) of this section.

MDPP services means structured health behavior change sessions that are furnished under the MDPP expanded model with the goal of preventing diabetes among Medicare beneficiaries with prediabetes, and that follow a CDC-approved curriculum. The sessions provide practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to maintaining weight loss and a healthy lifestyle.

MDPP services period means the time period, beginning on the date an MDPP beneficiary attends his or her first core session, over which the set of MDPP services is furnished to the MDPP beneficiary, to include the core services period described in paragraph (c)(2)(i) and,
subject to paragraph (c)(3) of this section, one or more ongoing maintenance session intervals during the ongoing services period described in paragraph (c)(2)(ii) of this section.

**MDPP session** means a core session, a core maintenance session, or an ongoing maintenance session.

**MDPP supplier** means an entity that is enrolled in Medicare to furnish MDPP services as provided in §424.205 of this chapter.

**Medicare Diabetes Prevention Program (MDPP)** refers to a model test expanded under section 1115A(c) of the Act that makes MDPP services available to MDPP beneficiaries.

* * * *

**Ongoing maintenance session** means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during an ongoing maintenance session interval;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for maintenance sessions.

**Ongoing maintenance session interval** means one of the up to eight consecutive 3-month time periods during the ongoing services period described in paragraph (c)(2)(ii) of this section, during which an MDPP supplier offers at least one ongoing maintenance session to an MDPP beneficiary per month.

* * * *

**Set of MDPP services** means the series of MDPP sessions, composed of core sessions, core maintenance sessions, and subject to paragraph (c)(3) of this section, ongoing maintenance sessions, offered over the course of the MDPP services period.
Virtual make-up session means a make-up session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for virtual sessions.

(c) Coverage for MDPP services.—

(1) Beneficiary eligibility. (i) A Medicare beneficiary is eligible for MDPP services offered during the core services period described in paragraph (c)(2)(i) of this section if the beneficiary meets all of the following criteria:

(A) Is enrolled under Medicare Part B;

(B) Attended the first core session within the most recent 12-month time period and, prior to attending this first core session, had not previously received the set of MDPP services in his or her lifetime;

(C) Has, on the date of attendance at the first core session, a body mass index (BMI) of at least 25 if not self-identified as Asian or a BMI of at least 23 if self-identified as Asian;

(D) Has received, within the 12-month time period prior to the date of attendance at the first core session, a hemoglobin A1c test with a value of between 5.7 and 6.4 percent, a fasting plasma glucose test with a value of between 110 and 125 mg/dL, or a 2-hour plasma glucose test (oral glucose tolerance test) with a value of between 140 and 199 mg/dL;

(E) Has, as of the date of attendance at the first core session, no previous diagnosis of diabetes, other than gestational diabetes; and

(F) Does not have end-stage renal disease (ESRD).

(ii) An MDPP beneficiary is eligible for the first ongoing maintenance session interval only if the beneficiary:

(A) Attends at least one in-person core maintenance session during the final core maintenance session interval; and
(B) Achieves or maintains the required minimum weight loss at a minimum of one in-person core maintenance session during the final core maintenance session interval.

(iii) An MDPP beneficiary is eligible for a subsequent ongoing maintenance session interval only if the beneficiary:

(A) Attends at least three ongoing maintenance sessions during the previous ongoing maintenance session interval, including at least one in-person ongoing maintenance session; and

(B) Maintains the required minimum weight loss at a minimum of one in-person ongoing maintenance session furnished during the previous ongoing maintenance session interval.

(iv) Weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session.

(2) **MDPP services period.** An MDPP beneficiary’s MDPP services period is composed of the following periods and intervals:

(i) The core services period, which is the first 12 months of the MDPP services period, and consists of:

(A) At least 16 core sessions offered at least one week apart during months 1 through 6 of the MDPP services period; and

(B) Two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period.

(ii) Subject to paragraph (c)(3) of this section, the ongoing services period, which consists of up to eight 3-month ongoing maintenance session intervals offered during months 13 through 36 of the MDPP services period.
(3) Limitations on the MDPP services period. (i) The MDPP services period ends upon completion of the core services period described in paragraph (c)(2)(i) of this section, unless the MDPP beneficiary qualifies for the first ongoing maintenance session interval, in accordance with paragraph (c)(1)(ii) of this section.

(ii) If the MDPP beneficiary qualifies for the first ongoing maintenance session interval as described in paragraph (c)(3)(i) of this section, the MDPP services period ends upon completion of this first ongoing maintenance session interval or any subsequent ongoing maintenance session interval, unless the beneficiary meets the eligibility requirements under paragraph (c)(1)(iii) of this section.

(iii) Unless sooner ended in accordance with this paragraph (c)(3), the MDPP services period ends automatically upon the completion of the eighth ongoing maintenance session interval.

(d) Make-up sessions. (1) An MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. If an MDPP supplier offers one or more make-up sessions to an MDPP beneficiary, each such session must be furnished in accordance with the following requirements:

(i) The curriculum furnished during the make-up session must address the same CDC-approved DPP curriculum topic as the regularly scheduled session that the beneficiary missed;

(ii) The MDPP supplier may furnish to the beneficiary a maximum of one make-up session on the same day as a regularly scheduled session; and

(iii) The MDPP supplier may furnish to the beneficiary a maximum of one make-up session per week.
(2) An MDPP supplier may offer virtual make-up sessions only if consistent with the requirements in paragraph (d)(1) of this section. Virtual make-up sessions are also subject to the following requirements:

(i) Virtual make-up sessions must be furnished in a manner consistent with the DPRP standards for virtual sessions;

(ii) An MDPP supplier may only offer virtual make-up sessions based on an individual MDPP beneficiary’s request; and

(iii) An MDPP supplier may offer to an MDPP beneficiary:

(A) No more than 4 virtual make-up sessions within the core services period described in paragraph (c)(2)(i) of this section, of which no more than 2 virtual make-up sessions are core maintenance sessions; and

(B) No more than 3 virtual make-up sessions that are ongoing maintenance sessions during any rolling 12-month time period.

(3) Make-up sessions furnished in accordance with paragraph (d)(1) of this section that an MDPP beneficiary attends in person are counted toward meeting the attendance requirements described in paragraph (c)(1) of this section and toward achieving the performance goals described in §414.84(b) of this chapter as if the MDPP beneficiary attended a regularly scheduled session. Virtual make-up sessions furnished in accordance with paragraph (d)(2) of this section are also counted toward such attendance requirements and performance goals, subject to the following limitations:

(i) The MDPP beneficiary receives no more than 4 virtual make-up sessions within the core services period described in paragraph (c)(2)(i) of this section, of which no more than 2 virtual make-up sessions may be core maintenance sessions; and
(ii) The MDPP beneficiary receives no more than 3 virtual make-up sessions that are ongoing maintenance sessions during any rolling 12-month period.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

6. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

7. Section 414.84 is added to read as follows:

§414.84 Payment for MDPP services.

(a) Definitions. In addition to the definitions specified at §§410.79 (b) and 424.205(a) of this chapter, the following definitions apply to this section.

Bridge payment means a one-time payment to an MDPP supplier for furnishing its first MDDP session to an MDPP beneficiary who has previously received one or more MDPP services from a different MDPP supplier.

Performance goal means an attendance or weight-loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment.

Performance payment means a payment made to an MDPP supplier for furnishing certain MDPP services to an MDPP beneficiary when the MDPP beneficiary achieves the applicable performance goal.

(b) Performance payment. CMS makes one or more types of performance payments to an MDPP supplier as specified in this paragraph. Each type of performance payment is made only if the beneficiary achieves the applicable performance goal and only once per MDPP beneficiary. A performance payment is made only on an assignment-related basis in accordance
with §424.55 of this chapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make a performance payment only to an MDPP supplier that complies with all applicable enrollment and program requirements and only for MDPP services that are furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished each session on the claim for the MDPP session. The seven types of performance payments are as follows:

1. Performance Goal 1: Attends the first core session that initiates the MDPP services period. CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary attends the first core session, which initiates the MDPP services period, and that first core session was furnished by that supplier. An MDPP supplier who has been paid this performance payment for an MDPP beneficiary is not eligible to be paid a bridge payment described in paragraph (c) of this section for that MDPP beneficiary. The amount of this performance payment is determined as follows:

   (i) For a first core session furnished April 1 through December 31, 2018, the amount of the performance payment is $25.

   (ii) For a first core session furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

2. Performance Goal 2: Attends four core sessions. CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary achieves attendance at the beneficiary’s
fourth core session upon attendance at a core session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For a fourth core session furnished April 1 through December 31, 2018, the amount of the performance payment is $30.

(ii) For a fourth core session furnished during a calendar year subsequent to CY 2018, the performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(3) **Performance Goal 3: Attends nine core sessions.** CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary achieves attendance at the ninth core session upon the beneficiary’s attendance at a core session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For a ninth core session furnished April 1 through December 31, 2018, the amount of the performance payment is $50.

(ii) For a ninth core session furnished during a calendar year subsequent to CY 2018, the performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(4) **Performance Goal 4: Attends three core maintenance sessions during a core maintenance session interval.** CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary attends three core maintenance sessions in a core maintenance session interval and achieves attendance at that third core maintenance session upon attendance at a core maintenance session furnished by that supplier. CMS makes this performance payment to an MDPP supplier only once per MDPP beneficiary per core maintenance session interval. The amount of this performance payment is determined as follows:
(i) If the beneficiary also achieves or maintains the required minimum weight loss as measured in-person during a core maintenance session furnished during the applicable core maintenance session interval:

(A) For a third core maintenance session furnished April 1 through December 31, 2018, the amount of the performance payment is $60.

(B) For a third core maintenance session furnished during a calendar year subsequent to CY 2018, the performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(ii) If the beneficiary does not achieve or maintain the required minimum weight loss as measured in-person during a core maintenance session furnished during the applicable core maintenance session interval:

(A) For a third core maintenance session furnished April 1 through December 31, 2018, the amount of the performance payment is $10.

(B) For a third core maintenance session furnished during a calendar year subsequent to CY 2018, the performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(5) Performance Goal 5: Attends three ongoing maintenance sessions and maintains the required minimum weight loss within an ongoing maintenance session interval. CMS makes a payment to an MDPP supplier if an MDPP beneficiary attends three ongoing maintenance sessions during an ongoing maintenance session interval, achieves attendance at that third ongoing maintenance session upon attendance at an ongoing maintenance session furnished by that supplier, and achieves or maintains the required minimum weight loss as measured in-person during an ongoing maintenance session furnished during the applicable ongoing maintenance
session interval. CMS makes this performance payment to an MDPP supplier only once per MDPP beneficiary per ongoing maintenance session interval. The amount of this performance payment is determined as follows:

(i) For a third ongoing maintenance session furnished April 1 through December 31, 2018, the amount of the performance payment is $50.

(ii) For a third ongoing maintenance session furnished during a calendar year subsequent to CY 2018, the performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(6) Performance Goal 6: Achieves the required minimum weight loss. CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves the required minimum weight loss as measured in-person during a core session or core maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

(i) For a core session or core maintenance session, as applicable, furnished April 1 through December 31, 2018, the amount of the performance payment is $160.

(ii) For a core session or core maintenance session, as applicable, furnished during a calendar year subsequent to CY 2018, the performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(7) Performance Goal 7: Achieves 9-percent weight loss. CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves at least a 9-percent weight loss as measured in-person during a core session, core maintenance session, or ongoing maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:
(i) For a core session, core maintenance session, or ongoing maintenance session, as applicable, furnished April 1 through December 31, 2018, the amount of the performance payment is $25.

(ii) For a core session, core maintenance session, or ongoing maintenance session, as applicable, furnished during a calendar year subsequent to CY 2018, the performance payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(c) Bridge payment. CMS makes a bridge payment to an MDPP supplier only for a core session, core maintenance session, or ongoing maintenance session furnished to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier. An MDPP supplier who has previously been paid either a bridge payment or a performance payment for an MDPP beneficiary is not eligible to be paid a bridge payment for that beneficiary. A bridge payment is made only on an assignment-related basis in accordance with §424.55 of this chapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make a bridge payment only to an MDPP supplier that complies with all applicable enrollment and program requirements, and only for MDPP services furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished the session on the claim for the MDPP session. The amount of the bridge payment is determined as follows:

(1) For a core session, core maintenance session, or ongoing maintenance session furnished April 1 through December 31, 2018, the amount of the bridge payment is $25.
(2) For a core session, core maintenance session, or ongoing maintenance session furnished during a calendar year subsequent to CY 2018, the bridge payment amount specified in this paragraph for the prior year, adjusted as specified in paragraph (d) of this section.

(d) Updating performance payments and the bridge payment. The performance payments and bridge payment will be adjusted each calendar year by the percent change in the Consumer Price Index for All Urban Consumers (CPI-U) (U.S. city average) for the 12-month period ending June 30th of the year preceding the update year. The percent change update will be calculated based on the level of precision of the index as published by the Bureau of Labor Statistics and applied based on one decimal place of precision. The annual MDPP services payment update will be published by CMS transmittal.

§414.90 Physician Quality Reporting System (PQRS).

*(j) Report at least 6 measures AND report each measure for at least 50 percent of the eligible professional’s Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, AND report each measure
for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).

(ii) (*)

(A) (*)

(1) (i) Report at least 6 measures AND report each measure for at least 50 percent of the eligible professional’s Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies.

(ii) (*)

(2) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted (unless they are inverse measures where a lower rate reflects better performance).

(iii) Via EHR direct product. For the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If an eligible professional’s direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the eligible professional must report all of the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.
(iv) Via EHR data submission vendor. For the 12-month 2018 PQRS payment adjustment reporting period, report at least 6 measures. If an eligible professional’s direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the eligible professional must report all of the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(9) * * *

(ii) Via qualified registry. For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report at least 6 measures AND report each measure for at least 50 percent of the group practice’s Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted (unless they are inverse measures where a lower rate reflects better performance).

(iii) Via EHR direct product. For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If the group practice’s direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.
(iv) **Via EHR data submission vendor.** For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report 6 measures. If the group practice’s direct EHR product or EHR data submission vendor product does not contain patient data for at least 6 measures, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) **Via a certified survey vendor in addition to a qualified registry.** For a group practice of 2 or more eligible professionals that elects to report via a certified survey vendor in addition to a qualified registry for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report at least 3 additional measures using the qualified registry AND report each measure for at least 50 percent of the group practice’s Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. If less than 3 measures apply to the group practice, the group practice must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B Fee-for-Service patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted (unless they are inverse measures where a lower rate reflects better performance).

(vi) **Via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor.** For a group practice of 2 or more eligible professionals that elects to report via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor.
In addition, the group practice must report at least 3 additional measures using the direct EHR product or EHR data submission vendor product. If less than 3 measures apply to the group practice, the group practice must report all of the measures for which there is patient data. Of the additional 3 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice must report on at least 1 measure for which there is Medicare patient data.

* * * * * *

(viii) If the CAHPS for PQRS survey is applicable to the practice, group practices comprised of 100 or more eligible professionals that register to participate in the GPRO may administer the CAHPS for PQRS survey, regardless of the GPRO reporting mechanism selected.

(k) * * *

(3) Satisfactory participation criteria for individual eligible professionals for the 2016 PQRS payment adjustment. * * *

* * * * *

(5) * * *

(i) Individual eligible professional. For the applicable 12-month reporting period, report at least 6 measures available for reporting under a QCDR AND report each measure for at least 50 percent of the eligible professional’s patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, AND report each measure for at least 50 percent of the eligible professional’s patients.

(ii) Group practices. For the applicable 12-month reporting period, report at least 6 measures available for reporting under a QCDR AND report each measure for at least 50 percent
of the group practice’s patients seen during the reporting period to which the measure applies. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable, AND report each measure for at least 50 percent of the group practice’s patients. If a group practice reports the CAHPS for PQRS survey measures, apply reduced criteria as follows: 3 measures, as applicable.

* * * * *

9. Section 414.94 is amended by revising paragraph (i)(3) and adding paragraphs (j) and (k) to read as follows:

§414.94 Appropriate use criteria for advanced diagnostic imaging services.

* * * * *

(i) * * * *

(3) The significant hardship exception applies to ordering professionals who:

(i) Are granted re-weighting of the advancing care information performance category to zero percent of the final score for the year under MIPS pursuant to §414.1380(c)(2) due to circumstances that include the criteria listed in §495.102(d)(4)(i) and (iii) and (d)(4)(iv)(A) and (B) of this chapter. The AUC significant hardship exception is available for the same period the re-weight is applied for purposes of the MIPS payment adjustments, or

(ii) Demonstrate a significant hardship consistent with the criteria listed in §495.102(d)(4)(i) and (iii) and (d)(4)(iv)(A) or (B) of this chapter. The AUC significant hardship exception may be available for a period no longer than 12 months.

(j) Consulting. Ordering Professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2019.
(k) **Reporting.** Furnishing Professionals must report the following information on Medicare claims for advanced diagnostic imaging services furnished in an applicable setting, paid for under an applicable payment system defined in §414.94(b), and ordered on or after January 1, 2019:

1. The qualified CDSM consulted by the ordering professional.
2. Information indicating:
   a. Whether the service ordered would adhere to specified applicable AUC;
   b. Whether the service ordered would not adhere to specified applicable AUC, or
   c. Whether the specified applicable AUC consulted was not applicable to the service ordered.
3. The NPI of the ordering professional who consulted specified applicable AUC as required in paragraph (j) of this section, if different from the furnishing professional.

10. Section 414.904 is amended by revising paragraph (e)(2) to read as follows:

    **§414.904 Average sales price as the basis for payment.**

    * * * * * *

    (e) * * *

    (2) **Infusion drugs furnished through a covered item of durable medical equipment.** The payment limit for an infusion drug furnished before January 1, 2017, through a covered item of durable medical equipment is calculated using 95 percent of the average wholesale price in effect on October 1, 2003.

    * * * * * *

11. Section 414.1270 is amended by revising paragraph (d)(1) to read as follows:
§414.1270 Determination and calculation of the Value-Based Payment Modifier adjustments.

(d) * * *

(1) A downward payment adjustment of −1.0 percent will be applied to a solo practitioner, a group with two to nine eligible professionals, and a group consisting only of nonphysician eligible professionals subject to the value-based payment modifier and no physicians; and a downward payment adjustment of −2.0 percent will be applied to a group with 10 or more eligible professionals and at least one physician if, during the applicable performance period as defined in §414.1215, the following apply:

   (i) For groups:

      (A) Such group does not meet the criteria as a group to avoid the PQRS payment adjustment for CY 2018 as specified by CMS; and

      (B) Fifty percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2018 as specified by CMS.

   (ii) For solo practitioners, such solo practitioner does not meet the criteria as an individual to avoid the PQRS payment adjustment for CY 2018 as specified by CMS.

* * *

12. Section 414.1275 is amended by revising paragraphs (c)(4) and (d)(3)(i) and (ii) to read as follows:

§414.1275 Value-based payment modifier quality-tiering scoring methodology.

(c) * * *

* * *
The following value-based payment modifier percentages apply to the CY 2018 payment adjustment period, for physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists who are solo practitioners or who are in groups of any size:

**CY 2018 Value-Based Payment Modifier Amounts for the Quality-Tiering Approach for Physicians, Physician Assistants, Nurse Practitioners, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists**

<table>
<thead>
<tr>
<th>Cost/quality</th>
<th>Low quality</th>
<th>Average quality</th>
<th>High quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Cost</td>
<td>+0.0%</td>
<td>+1.0x*</td>
<td>+2.0x*</td>
</tr>
<tr>
<td>Average Cost</td>
<td>+0.0%</td>
<td>+0.0%</td>
<td>+1.0x*</td>
</tr>
<tr>
<td>High Cost</td>
<td>+0.0%</td>
<td>+0.0%</td>
<td>+0.0%</td>
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</table>

*Eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where ‘x’ represents the upward payment adjustment factor.

(d) * * *

(3) * * *

(i) Classified as high quality/low cost receive an upward adjustment of +3x (rather than +2x); and

(ii) Classified as either high quality/average cost or average quality/low cost receive an upward adjustment of +2x (rather than +1x).

**PART 424—CONDITIONS FOR MEDICARE PAYMENT**

13. The authority citation for part 424 continues to read as follows:

**Authority**: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

14. Section 424.55 is amended by adding paragraph (d) to read as follows:

§424.55 Payment to the supplier.

* * *
(d) For purposes of claims for services submitted by an MDDP supplier (as defined at §410.79(b)), Medicare deems such claims to have been assigned by the beneficiary (or the person authorized to request payment on the beneficiary's behalf) and the assignment accepted by the MDDP supplier.

§ 424.59 [Removed]

15. Remove § 424.59.

16. Subpart I, consisting of §§ 424.200 through 424.210, is added to read as follows:

Subpart I—Requirements for Medicare Diabetes Prevention Program Suppliers and Beneficiary Engagement Incentives under the Medicare Diabetes Prevention Program Expanded Model

Sec.

424.200 Scope.
424.205 Requirements for Medicare Diabetes Prevention Program suppliers.
424.210 Beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

Subpart I—Requirements for Medicare Diabetes Prevention Program Suppliers and Beneficiary Engagement Incentives under the Medicare Diabetes Prevention Program Expanded Model

§424.200 Scope.

This subpart specifies the requirements for Medicare Diabetes Prevention Program suppliers and beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

§424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

(a) Definitions. In addition to the definitions specified at §§ 410.79(b) and 414.84(a) of this subchapter, the following definitions apply to this section:
**Administrative location** means a physical location associated with the MDPP supplier’s operations, from where coaches are dispatched or based, and where MDPP services may or may not be furnished.

**Coach** means an individual who furnishes MDPP services on behalf of an MDPP supplier as an employee, contractor, or volunteer.

**Coach eligibility end date** means the end date indicated by the MDPP supplier in submitting a change to the supplier’s MDPP enrollment application in accordance with paragraph (d)(5) of this section that removed the coach’s information, or the date the supplier itself was revoked from or withdrew its Medicare enrollment as an MDPP supplier.

**Coach eligibility start date** means the start date indicated by the MDPP supplier when submitting an eligible the coach’s information on the MDPP enrollment application.

**Community setting** means a location where the MDPP supplier furnishes MDPP services outside of their administrative locations. A community setting is a location open to the public not primarily associated with the supplier. Community settings may include, for example, church basements or multipurpose rooms in recreation centers.

**Eligible coach** means an individual who CMS has screened and has determined can provide MDPP services on behalf of an MDPP supplier in accordance with paragraph (e) of this section.

**Ineligible coach** means an individual whom CMS has screened and has determined cannot provide MDPP services on behalf of an MDPP supplier in accordance with paragraph (e) of this section.

**MDPP interim preliminary recognition** means a status that CMS has granted to an entity in accordance with paragraph (c) of this section.
(b) **Conditions for MDPP supplier enrollment.** An entity may enroll as an MDPP supplier only if it satisfies the following requirements and all other applicable Medicare enrollment requirements:

1. Has either an MDPP preliminary recognition, as defined in paragraph (c)(1) of this section or a full CDC DPRP recognition.
2. Maintains an active and valid TIN and NPI at the organizational level.
3. Has passed screening requirements as follows:
   - (i) Upon initial enrollment, at a “high” categorical risk in accordance with §424.518(c)(2); and
   - (ii) Upon revalidation, at a “moderate” categorical risk in accordance with §424.518(b)(2).
4. Maintains, and submits to CMS through the CMS-approved enrollment application, a roster of all coaches who will be furnishing MDPP services on the entity’s behalf that includes each coach’s first and last names, middle initial (if applicable), date of birth, Social Security Number (SSN), active and valid NPI, coach eligibility start date, and coach eligibility end date (if applicable). This roster must be updated in accordance with paragraph (d)(5) of this section.
5. Meets and certifies in its CMS-approved enrollment application that it meets and will continue to meet the supplier enrollment standards described in paragraph (d) of this section.
6. Revalidates its Medicare enrollment every 3 years after the effective date of enrollment.

(c) **MDPP preliminary recognition.** (1) For the purposes of this section, an MDPP preliminary recognition may include either:

   - (i) Any preliminary recognition established by CDC for the purposes of the DPRP; or
(ii) An MDPP interim preliminary recognition.

(A) MDPP interim preliminary recognition application period. Entities may apply to
CDC for CMS’ MDPP interim preliminary by submitting information at the time and in the form
and manner specified by CMS.

(B) MDPP Interim preliminary recognition requirements. An entity may qualify for
MDPP interim preliminary recognition if--

(1) The entity has pending CDC recognition.

(2) The entity submits a full 12 months of performance data to CDC on at least one
completed cohort. The 12 month data submission includes at least 5 participants who attended at
least 3 sessions in the first 6 months and whose time from first session attended to last session of
the lifestyle change program was at least 9 months, at least 60 percent of whom attended at least
9 sessions in months 1 through 6, and at least 60 percent of whom attended at least 3 sessions in
months 7 through 12.

(2) [Reserved]

(d) Medicare Diabetes Prevention Program supplier standards. An MDPP supplier must
meet and must certify in its CMS-approved enrollment application that it meets and will continue
to meet the following standards.

(1) The MDPP supplier must have and maintain MDPP preliminary recognition, as
defined under paragraph (c)(1) of this section, or a full CDC DPRP recognition.

(2) The MDPP supplier must not currently have its billing privileges terminated for-
cause or be excluded by a State Medicaid agency.

(3) The MDPP supplier must not include on the roster of coaches, described in paragraph
(b)(4) of this section and updated in accordance with paragraph (d)(5) of this section, nor permit
MDPP services to be furnished by any individual coach who meets any of ineligibility criteria outlined in paragraph (e)(1) of this section.

(4) The MDPP supplier must maintain at least one administrative location. All administrative locations maintained by the MDPP supplier must be located at an appropriate site and be reported on the CMS-approved enrollment application. An appropriate site for such an administrative location would include all of the following characteristics:

   (i) Signage posted on the exterior of the building. Such signage may include, for example, the MDPP supplier’s legal business name or DBA, as well as hours of operation.

   (ii) Open for business during stated operational hours.

   (iii) Employees, staff, or volunteers present during operational hours; and

   (iv) Not a private residence.

(5) The MDPP supplier must update its enrollment application within 30 days of any changes of ownership, changes to the coach roster (including due to coach ineligibility or because the coach is no longer an employee, contractor, or volunteer of the MDPP supplier), and final adverse action history, and report all other changes, including but not limited to changes in the MDPP supplier’s administrative location(s), to CMS within 90 days of the reportable event.

(6) The MDPP supplier must maintain a primary business telephone that operates either at administrative locations described in paragraph (d)(4) of this section or directly where services are furnished, if services are furnished in community settings. The associated telephone number must be listed with the either the legal or doing business as name of the supplier in public view, including on websites, flyers, and materials.

(7) The MDPP supplier must not knowingly sell to or allow another individual or entity to use its supplier billing number.
(8) Subject to paragraph (d)(8)(i) of this section, the MDPP supplier must not deny an MDPP beneficiary access to MDPP services during the MDPP services period described in §410.79(c)(2) of this chapter, including on the basis of the beneficiary’s weight, health status, or achievement of performance goals.

(i) Suppliers may deny an MDPP beneficiary access to MDPP services during the MDPP services period only under one of the following conditions:

(A) The MDPP beneficiary no longer meets the eligibility criteria for MDPP services under §410.79(c)(1) of this chapter.

(B) The MDPP supplier lacks the self-determined capacity to furnish MDPP services to additional MDPP beneficiaries.

(C) The MDPP supplier determines that the MDPP beneficiary significantly disrupts the session for other MDPP beneficiaries or becomes abusive.

(ii) MDPP suppliers must maintain a record of the number of MDPP beneficiaries turned away for the reasons outlined in paragraphs (d)(8)(i)(B) and (C) of this section, to include the date each such beneficiary was turned away. For beneficiaries turned away for reasons described in paragraph (d)(8)(i)(C) of this section, the MDPP supplier must document details of the occurrence(s), including date(s) of the behavior, any remediation efforts taken by the MDPP supplier, and final action (for example, dismissal from an MDPP session or denial from future sessions) in the beneficiary’s MDPP records.

(9) The MDPP supplier and other individuals or entities performing functions or services related to MDPP services on the MDPP supplier’s behalf must not unduly coerce an MDPP beneficiary’s decision to change or not to change to a different MDPP supplier, including through the use of pressure, intimidation, or bribery.
(10) Except as allowed under paragraph (d)(8) of this section, the MDPP supplier must offer an MDPP beneficiary no fewer than all of the following:

(i) Sixteen in-person core sessions no more frequently than weekly for the first 6 months of the MDPP services period, which begins on the date of attendance at the first such core session.

(ii) One in-person core maintenance session each month during months 7 through 12 (6 months total) of the MDPP services period.

(iii) One in-person ongoing maintenance session each month for months 13 through 36 of the MDPP services period, as long as the beneficiary maintains eligibility to receive such services in accordance with §410.79(c)(1)(ii) and (iii) of this chapter.

(11) Before the initial core session is furnished, the MDPP supplier must disclose detailed information about the set of MDPP services to each MDPP beneficiary to whom it wishes to begin furnishing MDPP services. Such information must include all of the following:

(i) Eligibility requirements under §410.79(c)(1) of this chapter, including the once-per-lifetime nature of MDPP services.

(ii) The MDPP supplier standards as outlined in this section.

(12) The MDPP supplier must answer MDPP beneficiaries’ questions about MDPP services and respond to MDPP-related complaints within a reasonable timeframe. An MDPP supplier must implement a complaint resolution protocol and maintain documentation of all beneficiary contact regarding such complaints, including the name and Medicare Beneficiary Identifier of the beneficiary, a summary of the complaint, related correspondences, notes of actions taken, and the names and/or NPIs of individuals who took such actions on behalf of the MDPP supplier. Failure to maintain a complaint resolution protocol or to retain information
regarding MDPP related complaints in accordance with paragraph (g) of this section may be considered evidence that the MPPP supplier standards have not been met. This information must be kept at each administrative location and made available to CMS or its contractors upon request.

(13) The MDPP supplier must maintain a crosswalk file which indicates how beneficiary identifications for the purposes of CDC performance data requirements correspond to corresponding beneficiary health insurance claims numbers or Medicare Beneficiary Identifiers for each MDPP beneficiary receiving MDPP services from the MDPP supplier. The MDPP supplier must submit the crosswalk file to CMS or its contractor.

(14) The MDPP supplier must submit performance data for MDPP beneficiaries who attend ongoing maintenance sessions with data elements consistent with the CDC’s DPRP standards for data elements required for the core services period.

(15) The MDPP supplier must allow CMS or its agents to conduct onsite inspections or recordkeeping reviews in order to ascertain the MDPP supplier’s compliance with these standards, and must adhere to the documentation requirements as outlined in paragraph (g) of this section.

(e) Coach eligibility—(1) Criteria. To furnish MDPP services to a beneficiary, an MDPP coach must not:

(i) Currently have Medicare billing privileges revoked and be currently subject to the reenrollment bar.

(ii) Currently have its Medicaid billing privileges terminated for-cause or be excluded by a State Medicaid agency.
(iii) Currently be excluded from any other Federal health care program, as defined in 42 CFR 1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(iv) Currently be debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement program or activity in accordance with the Federal Acquisition Streamlining Act implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.

(v) Have, in the previous 10 years, one of the following State or Federal felony convictions:

(A) Crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

(C) Any felony that placed the Medicare or its beneficiaries at immediate risk, such as a malpractice suit that results in the individual being convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion of criminal neglect or misconduct.

(D) Any felonies for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion that would result in mandatory exclusion under section 1128(a) of the Act.

(2) CMS determination of coach eligibility. CMS will screen each individual identified on the roster of coaches included with the supplier’s enrollment application described in
paragraph (b)(4) of this section and updated in accordance with paragraph (d)(5) of this section to verify that the individual coach does not meet any of the conditions specified in paragraph (e)(1) of this section and that the coach can provide MDPP services on behalf of an MDPP supplier. For each individual coach successfully screened by CMS, his or her eligibility start date becomes effective and remains effective until an MDPP supplier or CMS takes action that results in an eligibility end date.

(f) Effective date for billing privileges. (1) For MDPP suppliers initially enrolling and for newly established administrative locations that result in a new enrollment record or Provider Transaction Access Number, the effective date for Medicare billing privileges for MDPP suppliers is --

(i) The later of --

(A) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor;

(B) The date of filing of a corrective action plan that was subsequently approved by a Medicare contractor; or

(C) The date that the supplier first began furnishing services at a new administrative location that resulted in a new enrollment record or Provider Transaction Access Number

(ii) Under no circumstances should the effective date of billing privileges for any MDPP supplier be prior to April 1, 2018

(2) For any newly established administrative locations that do not result in a new enrollment record or Provider Transaction Access Number, the existing billing privilege effective date for their Provider Transaction Access Number will apply, but not earlier than April 1, 2018.
(g) Documentation retention and provision requirements. An MDPP supplier must maintain all documentation related to participation in the MDPP in accordance with all applicable Federal and State laws. The MDPP supplier must provide to CMS, a contractor acting on CMS’ behalf, the Office of the Inspector General, and the Comptroller General or their designee(s) scheduled and unscheduled access to the MDPP supplier’s records, including, but not limited to, all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the MDPP supplier’s compliance with the MDPP expanded model’s requirements, including the MDPP expanded model requirements for in-kind beneficiary incentive engagements in §424.210 of this chapter in the event that the MDPP supplier chooses to offer such incentives to any MDPP beneficiary.

(1) The documentation for the first core session must be established contemporaneous with the furnishing of MDPP services and must include at least all of the following:

(i) Organizational information, including MDPP supplier name, CDC DPRP number, and NPI.

(ii) Basic beneficiary information for each MDPP beneficiary in attendance, including but not limited to beneficiary name, HICN, age.

(iii) Evidence that each such beneficiary satisfied the eligibility requirements under §410.79(c) at the time of service.

(2) The documentation for each MDPP session attended must be established contemporaneous with the furnishing of MDPP services and must include at least all of the following:
(i) Documentation of the type of session, whether a core session, a core maintenance session, an ongoing maintenance session, an in-person make-up session, or a virtual make-up session.

(ii) Identification of which CDC-approved DPRP curriculum was associated with the session.

(iii) The NPI of the coach who furnished the session.

(iv) The date and place of service of the session.

(v) Each MDPP’s beneficiary’s weight and date weight taken, in a form and manner as specified by CMS.

(3) If an MDPP supplier chooses to offer in-kind beneficiary engagement incentives to MDPP beneficiaries as permitted under §424.210, the records maintained by the MDPP supplier in accordance with this section must also include the information required by §424.210(e).

(4) An MDPP supplier is required to maintain and handle any beneficiary Personally Identifiable Information (PII) and Protected Health Information (PHI) in compliance with HIPAA, other applicable state and federal privacy laws, and CMS standards.

(5) The MDPP supplier’s records must include an attestation from the MDPP supplier that, as applicable, the MDPP beneficiary for which it is submitting a claim—

(i) Has attended their first, fourth or ninth core session, as applicable, if the claim submitted is for a performance payment under §414.84(b)(1), (2), or (3) of this chapter.

(ii) Has attended at least three core maintenance sessions, achieved required minimum weight loss, or both, as applicable, if the claim submitted is for a performance payment under §414.84(b)(4) of this chapter.
(iii) Has achieved the required minimum weight loss and attended at least three ongoing maintenance sessions within an ongoing maintenance session interval, if the claim submitted is for a performance payment under §414.84(b)(5) of this chapter, if the claim submitted is for a performance payment under §414.84(b)(6) of this chapter.

(iv) Has achieved required minimum weight loss as measured in-person during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under §414.84(b)(6) of this chapter.

(v) Has achieved at least a 9-percent weight loss percentage as measured in-person during a core session, core maintenance session, or ongoing maintenance session furnished by that supplier, if the claim submitted is for a performance payment under §414.84(b)(7) of this chapter.

(6) The MDPP supplier must maintain all records required under this section for a period of 10 years from the last day of the MDPP beneficiary’s receipt of MDPP services provided by the MDPP supplier or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless either of the following apply:

(i) CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the MDPP supplier at least 30 calendar days before the normal disposition rate; or

(ii) There has been a dispute or allegation of fraud or similar fault against the MDPP supplier, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault, as defined at §405.902 of this chapter.
(h) Denial or revocation of MDPP supplier enrollment. (1) An MDPP supplier is subject to enrollment denial or revocation of its MDPP supplier enrollment for one or more of the following reasons:

(i) Failure to meet enrollment requirements. The MDPP supplier does not satisfy the conditions specified in paragraph (b) of this section.

(A) An enrollment denial under this paragraph (h)(1)(i) is considered an enrollment denial under §424.530(a)(1) of this chapter.

(B) A revocation under this paragraph (h)(1)(i) is considered a revocation under §424.535(a)(1) of this chapter.

(C) An MDPP supplier that does not satisfy the requirements in paragraph (b)(1) of this section may become eligible to bill for MDPP services again if it successfully achieves MDPP preliminary recognition or full CDC DPRP recognition, and successfully enrolls again in Medicare as an MDPP supplier after any applicable reenrollment bar has expired.

(ii) Failure to meet MDPP supplier standards. The MDPP supplier fails to meet the standards specified in paragraph (d) of this section.

(A) An enrollment denial under this paragraph (h)(1)(ii) is considered an enrollment denial under §424.530(a)(1) of this part.

(B) A revocation under this paragraph (h)(1)(ii) is considered a revocation under §424.535(a)(1) of this part.

(iii) Application of existing enrollment denial reasons. One of the enrollment denial reasons specified in §424.530(a) of this part applies.

(iv) Application of existing revocation reasons. One of the revocation reasons specified in §424.535(a) of this chapter applies.
(v) **Use of an ineligible coach.** (A) The MDPP supplier knowingly allows an ineligible coach to furnish MDPP services to Medicare beneficiaries. Knowingly means that the MDPP supplier received an enrollment denial or revocation notice based on failing to meet the standard specified in §424.205(d)(3), was provided notice by CMS or contractors working on its behalf of this coach’s ineligibility including the reason(s) for ineligibility, submitted a corrective action plan (CAP) to remove the coach and become compliant therefore maintaining its enrollment, but continued to allow the coach to provide MDPP services in violation of the CAP.

(B) Revocation under this paragraph (h)(1)(v) is subject to the following requirements:

1. The revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the MDPP supplier.

2. For the revocation authority under this paragraph, MDPP suppliers are barred from participating in the Medicare program from the date of the revocation, which begins 30 days after CMS or its contractor mails notice of the revocation, until the end of the reenrollment bar, which lasts a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation.

3. A revoked MDPP supplier must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter.

(2) An MDPP supplier may appeal an enrollment denial or revocation decision in accordance with the procedures specified in part 498 of this chapter. References to suppliers in that section apply to MDPP suppliers.

§424.210 **Beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.**
(a) **Definitions.** In addition to the definitions specified at §410.79(b) and §424.205(a) of this chapter, the following definition applies to this section:

*Engagement incentive period* means the period of time during which an MDPP supplier may furnish in-kind beneficiary engagement incentives to a given MDPP beneficiary to whom the MDPP supplier is furnishing MDPP services. This period begins when an MDPP supplier furnishes any MDPP service to an MDPP eligible beneficiary and ends when one of the following occurs, whichever occurs first:

(i) The MDPP beneficiary’s MDPP services period ends as described in §410.79(c)(3) of this chapter.

(ii) The MDPP supplier knows the MDPP beneficiary will no longer be receiving MDPP services from the MDPP supplier.

(iii) The MDPP supplier has not had direct contact, either in-person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period.

(b) **General.** An MDPP supplier may choose to furnish an item or service as an in-kind beneficiary engagement incentive to an MDPP beneficiary only during the engagement incentive period, subject to the following conditions:

(1) The item or service must be furnished directly to an MDPP beneficiary by an MDPP supplier or by an agent of the MDPP supplier, such as a coach, under the MDPP supplier’s direction and control.

(2) The item or service must be reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, a core maintenance session, or ongoing maintenance session furnished by the MDPP supplier.
(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as specified in paragraph (d) of this section, for an MDPP beneficiary by engaging him or her in better managing his or her own health.

(4) The item or service must not be tied to the receipt of services outside of the MDPP services.

(5) The item or service must not be tied to the receipt of services from a particular provider, supplier, or coach.

(6) The availability of the item or service must not be advertised or promoted as an in-kind beneficiary engagement incentive available to an MDPP beneficiary receiving MDPP services from the MDPP supplier except that an MDPP beneficiary may be made aware of the availability of the item or service at the time the MDPP beneficiary could reasonably benefit from it during the engagement incentive period.

(7) The cost of the item or service must not be shifted to another Federal health care program, as defined at section 1128B(f) of the Act.

(c) Technology furnished to an MDPP beneficiary. In-kind beneficiary engagement incentives involving technology furnished by an MDPP supplier to an MDPP beneficiary are subject to the following conditions:

(1) Items or services involving technology may not, in the aggregate, exceed $1,000 in retail value for any one MDPP beneficiary.

(2) Items or services involving technology must be the minimum necessary to advance a clinical goal, as listed in paragraph (d) of this section, for an MDPP beneficiary.

(3) Items involving technology exceeding $100 in retail value must—

(i) Remain the property of the MDPP supplier; and
(ii) Be retrieved from the MDPP beneficiary at the end of the engagement incentive period. The MDPP supplier must document all retrieval attempts, including the ultimate date of retrieval in accordance with paragraph (e)(3) of this section. Documented diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

(d) Clinical goals of the MDPP expanded model. The following are the clinical goals for MDPP beneficiaries, that may be advanced through in-kind beneficiary engagement incentives:

1. Attendance at core sessions, core maintenance sessions, or ongoing maintenance sessions.

2. Weight loss.

3. Long-term dietary change.

4. Adherence to long-term health behavior changes.

(e) Documentation of beneficiary engagement incentives. In addition to the documentation requirements at §424.205(g), an MDPP supplier must maintain documentation of items and services furnished as in-kind beneficiary engagement incentives that exceed $25 in retail value.

1. The documentation must be established contemporaneous with the furnishing of the in-kind items and services and must include at least the following:

   (i) The date the item or service is furnished.

   (ii) The identity of the MDPP beneficiary to whom the item or service is furnished.

   (iii) The agent of the MDPP supplier who furnished the item or service, if applicable.

   (iv) A description of the item or service.

   (v) The retail value of the item or service.
(vi) Documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period.

(2) Documentation regarding items or services that are furnished to the MDPP beneficiary for use on an ongoing basis during the engagement incentive period, including items of technology exceeding $100 in retail value, must also include contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary possesses or has access to the item or service furnished by the MDPP supplier.

(3) The documentation regarding items of technology exceeding $100 in retail value must also include contemporaneous documentation of any attempt to retrieve technology as required by paragraph (c)(3)(ii) of this section.

(4) The MDPP supplier must retain and provide access to the documentation required in this section in accordance with §424.205(g).

17. Section 424.502 is amended by revising the definition for “Institutional provider” to read as follows.

§424.502 Definitions.

* * * * *

Institutional provider means any provider or supplier that submits a paper Medicare enrollment application using the CMS-855A, CMS-855B (not including physician and nonphysician practitioner organizations), CMS-855S, any enrollment application designated for MDPP suppliers, or an associated Internet-based PECOS enrollment application.

* * * * *
18. Section 424.516 is amended by revising paragraph (e) introductory text to read as follows.

§424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(e) Reporting requirements for all other providers and suppliers. Reporting requirements for all other providers and suppliers not identified in paragraphs (a) through (d) of this section, with the exception of MDPP suppliers whose reporting requirements are established in §424.205(d), must report to CMS the following information within the specified timeframes:

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