

J. Proposed Expansion of the Diabetes Prevention Program (DPP) Model

1. Background

In January 2015, the Administration announced the vision of “Better Care, Smarter Spending, Healthier People” with emphases on improving the way providers are paid, improving and innovating in care delivery, and sharing information to support better decisions.

Diabetes is at epidemic levels in the Medicare population, affecting more than 25 percent of Americans aged 65 and older.⁹ Care for Americans aged 65 and older with diabetes accounts for roughly \$104 billion annually, and these costs are growing; by 2050, diabetes prevalence is projected to increase 2 to 3 fold if current trends continue.¹⁰ Fortunately, Type 2 diabetes is typically preventable with appropriate lifestyle changes.

A diabetes prevention program is an evidence-based intervention targeted to individuals with prediabetes, meaning those who have blood sugar that is higher than normal but not yet in the diabetes range. The risk of progression to Type 2 diabetes in an individual with prediabetes is around 5–10 percent per year, or about 5–20 times higher than in individuals with normal blood glucose.¹¹ The National Diabetes Prevention Program (DPP) administered by the Centers for Disease Control and Prevention (CDC), is a structured health behavior change program delivered in community and health care settings by trained community health workers or health professionals. The National DPP consists of 16 intensive “core” sessions of a CDC-approved curriculum in a group-based setting that provides practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to sustaining weight loss and a healthy lifestyle. After the 16 core sessions, monthly maintenance sessions help to ensure that the participants maintain healthy behaviors. The primary goal of the intervention is to reduce incidence of Type 2 diabetes by achieving at least 5 percent average weight loss among

participants. To learn more about the National DPP please visit <http://www.cdc.gov/diabetes/prevention/lifestyle-program/index.html>.

In 2012, the Center for Medicare & Medicaid Innovation (the Innovation Center) awarded a Health Care Innovation Award (HCIA) to The Young Men’s Christian Association (YMCA) of the USA (Y–USA) to test whether DPP services could be successfully furnished by non-physician, community-based organizations to Medicare beneficiaries diagnosed with prediabetes and therefore at high risk for development of Type 2 diabetes. The HCIA model tests are being conducted under the authority of section 1115A of the Act (added by section 3021 of the Affordable Care Act) (42 U.S.C. 1315a). The statute authorizes the Innovation Center to test innovative health care payment and service delivery models that have the potential to reduce Medicare, Medicaid, and Children’s Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of patient care.

Between February 2013 and June 2015, the Y–USA, in partnership with 17 local YMCAs, the Diabetes Prevention and Control Alliance, and seven other non-profit organizations, enrolled a total of 7,804 Medicare beneficiaries into the model. Enrolled beneficiaries represented a diverse geography across the eight states of Arizona, Delaware, Florida, Indiana, Minnesota, New York, Ohio, and Texas. According to the second year independent evaluation report of the Y–USA Diabetes Prevention Program model, Medicare beneficiaries demonstrated high rates of participation and sustained engagement in the Diabetes Prevention Program. Approximately 83 percent of recruited Medicare beneficiaries attended at least 4 core sessions and approximately 63 percent completed 9 or more core sessions. The first and second independent evaluation reports are available on the Innovation Center’s Web site at <https://innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/>.

2. Certification of the Medicare Diabetes Prevention Program (MDPP)

CMS’ Office of the Actuary has determined that DPP is likely to reduce Medicare expenditures if made available to eligible Medicare beneficiaries based on historical evidence from evaluations of the Y–USA DPP and other DPPs in the CDC Diabetes Prevention Recognition Program. In addition, to evaluate the longer-term impact of the program, the CMS Actuary developed a model to estimate lifetime per

participant savings of a Medicare beneficiary receiving DPP services.

The full CMS Actuary Report is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf>.

3. Requirements for Expansion

Section 1115A(c) of the Act provides the Secretary with the authority to expand (including implementation on a nationwide basis) through rulemaking the duration and scope of a model that is being tested under section 1115A(b) of the Act if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the expansion is expected to either reduce spending without reducing quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of benefits.

- *Improved Quality of Care without Increased Spending:* Weight loss is a key indicator of success among persons enrolled in a DPP. According to the second year independent evaluation of the Y–USA DPP HCIA project, those beneficiaries who attended at least one core session lost an average of 7.6 pounds while beneficiaries who attended at least four core sessions lost an average of 9 pounds. BMI was reduced from 32.9 to 31.5 among Medicare beneficiaries that attended at least four core sessions. Based on these findings and results from other DPP evaluations demonstrating the effectiveness of the program in preventing diabetes onset, the Secretary determined that expansion of the DPP will reduce spending and improve the quality of care.

- *Impact on Medicare Spending:* The CMS Chief Actuary has certified that expansion of the DPP would not result in an increase of Medicare spending.

- *No Alteration in Coverage or Provision of Benefits:* The DPP, if implemented in Medicare, would provide services in addition to existing Medicare services, and beneficiaries receiving DPP services would retain all benefits covered in traditional Medicare. Therefore, the Secretary has determined that expansion of DPP would not deny or limit the coverage or provision of Medicare benefits for Medicare beneficiaries.

⁹Centers for Medicare and Medicaid Services. Chronic Conditions among Medicare Beneficiaries, Chartbook, 2012 Edition. Baltimore, MD, 2012.

¹⁰Boyle, J.P., Thompson, T.J., Gregg, E.W., Barker, L.E., & Williamson, D.F. (2010). Projection of the year 2050 burden of diabetes in the US adult population: Dynamic modeling of incidence, mortality, and prediabetes prevalence. *Popul Health Metr*, 8(1), 29.

¹¹Zhang, X., Gregg, E.W., Williamson, D.F., Barker, L.E., Thomas, W., Bullard, K.M., & Albright, A.L. (2010). A1C level and future risk of diabetes: a systematic review. *Diabetes Care*, 33(7), 1665–1673.

4. Proposed Expansion of Medicare Diabetes Prevention Program

We propose to expand the duration and scope of the DPP model test by expanding DPP under section 1115A(c) of the Act, and we propose to refer to this expanded model as the Medicare Diabetes Prevention Program (MDPP). In this section of this proposed rule, we propose a basic framework for the MDPP. If finalized, we will engage in additional rulemaking, likely within the next year, to establish specific requirements of the MDPP. We seek comment on all of the proposals below and on any other policy or operational issues that need to be considered in implementing this expansion. The MDPP will become effective January 1, 2018.

• *MDPP as an “Additional Preventive Service” under section 1861(ddd) of the Act: CMS Authority to Designate MDPP as an “Additional Preventive Service”:* We propose to designate MDPP services as “additional preventive services” available under Medicare Part B. Section 1861(ddd) defines “additional preventive services” as services that are not preventive services or personalized prevention plan services (as those terms defined in section 1861(ddd)(3)(A) and (C)) that identify medical conditions or risk factors and that the Secretary determines are (A) reasonable and necessary for the prevention or early detection of an illness or disability; (B) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF); and (C) appropriate for individuals entitled to benefits under Part A or enrolled in Part B.

We believe that MDPP services are generally consistent with the types of additional preventive services that are appropriate for Medicare beneficiaries. In particular, we believe that MDPP services we are proposing under the expanded MDPP model meet the requirements of section 1861(ddd)(1)(A) of the Act because they are specifically designed to prevent prediabetes from advancing into diabetes. MDPP services do not meet the requirement in section 1861(ddd)(1)(B) of the Act that they have received a recommendation with a grade of A or B by the USPSTF. However, under section 1115A(d)(1) of the Act, the Secretary has authority to waive certain requirements. We propose to use this waiver authority to waive section 1861(ddd)(1)(B) of the Act with respect to MDPP services because they have been recommended by the Community Preventive Services Task Force, which is similar to the USPSTF,

and therefore a USPSTF recommendation is not necessary. We believe that MDPP services are appropriate for individuals entitled to benefits under part A or enrolled in Part B, and thus meet the requirements of section 1861(ddd)(1)(C) of the Act, because findings from the second year independent evaluation of the Y–USA DPP HCIA project and results from other DPP evaluations demonstrate effectiveness of the program in preventing diabetes onset and thus improve quality of care for Medicare beneficiaries.

Section 1861(ddd)(2) of the Act requires the Secretary to make the determinations required under section 1861(ddd)(1) of the Act using the process for making national coverage determinations (NCDs). However, we propose to waive this requirement because using the NCD process to implement the MDPP would create implementation problems, especially as this rule proposes to create a supplier class and this is an issue that the NCD process does not address.

We seek comment on these proposals.

MDPP Benefit Description: We propose MDPP to be a 12 month program using the CDC-approved DPP curriculum, consisting of 16 core sessions over 16–26 weeks and the option for monthly core maintenance sessions over 6 months thereafter if the beneficiary achieves and maintains a minimum weight loss in accordance with the CDC Diabetes Prevention Recognition Program Standards and Operating Procedures. CDC-approved DPP session curriculum requirements are detailed below.

CDC-Approved DPP Session Curriculum Requirements

During the first 6 months (weeks 1–26) of the DPP intervention, each of the 16 core sessions must address one of these curriculum topics, and all topics must be addressed by the end of the 16 sessions.

1. Welcome to the National Diabetes Prevention Program
2. Self-Monitoring Weight and Food Intake
3. Eating Less
4. Healthy Eating
5. Introduction to Physical Activity (Move Those Muscles)
6. Overcoming Barriers to Physical Activity (Being Active—A Way of Life)
7. Balancing Calorie Intake and Output
8. Environmental Cues to Eating and Physical Activity
9. Problem Solving
10. Strategies for Healthy Eating Out
11. Reversing Negative Thoughts

12. Dealing with Slips in Lifestyle Change

13. Mixing Up Your Physical Activity: Aerobic Fitness
14. Social Cues
15. Managing Stress
16. Staying Motivated, Program Wrap Up

The last 6 months (weeks 27–52) of the DPP 12-month intervention must include at least one core maintenance session delivered in each of the 6 months (for a minimum of six sessions), and all core maintenance sessions must address different topics.

1. Welcome to the Second Phase of the Program
2. Healthy Eating: Taking It One Meal at a Time
3. Making Active Choices
4. Balance Your Thoughts for Long-Term Maintenance
5. Healthy Eating With Variety and Balance
6. Handling Holidays, Vacations, and Special Events
7. More Volume, Fewer Calories (Adding Water Vegetables and Fiber)
8. Dietary Fats
9. Stress and Time Management
10. Healthy Cooking: Tips for Food Preparation and Recipe Modification
11. Physical Activity Barriers
12. Preventing Relapse
13. Heart Health
14. Life With Type 2 Diabetes
15. Looking Back and Looking Forward

CDC-approved curriculum can be found at http://www.cdc.gov/diabetes/prevention/pdf/curriculum_toc.pdf.

We propose that the MDPP expanded model will use the CDC-approved curriculum. We also propose that beneficiaries who meet the coverage criteria that we propose below would be able to enroll in the MDPP only once; however, we propose that those beneficiaries who complete the 12 month program and achieve and maintain a required minimum level of weight loss would be eligible for additional monthly maintenance sessions for as long as the weight loss is maintained. We propose that these ongoing maintenance sessions adhere to the same curriculum requirements as the core maintenance sessions. We propose to require that each MDPP session be at least an hour in duration.

We propose to describe the services that would be covered under the Medicare Diabetes Prevention Program expanded model at \$ 410.79. Consistent with our statutory authority, we will continue to test and evaluate the nationwide MDPP as finalized. In the

future, we will assess whether the nationwide implementation of the MDPP is continuing to reduce Medicare spending without reducing quality of care or improve the quality of patient care without increasing spending, and could modify the nationwide MDPP as appropriate. We seek comment on this proposal.

- *Enrollment of New Medicare Suppliers:*

- MDPP Supplier Enrollment*

Requirements: As of 2015, more than 800 organizations have preliminary or full recognition from the CDC Diabetes Prevention Recognition Program (DPRP) to provide DPP services. These organizations have served more than 40,000 participants. More than 60 health plans provide some coverage of DPP services.

We propose that any organization recognized by the CDC (that is, those with preliminary or full recognition) to provide DPP services would be eligible to apply for enrollment in Medicare as a supplier beginning on or after January 1, 2017. This proposal would promote timely enrollment of CDC-recognized organizations before billing begins, and would permit full implementation of the MDPP expansion by January 1, 2018.

We propose that MDPP suppliers would be subject to the enrollment regulations set forth in 42 CFR part 424, subpart P. Organizations seeking to enroll in Medicare specifically to become MDPP Suppliers would be subject to screening under § 424.518. We are considering what level of application screening is most appropriate, and we are currently proposing that potential MDPP

Suppliers be screened according to the high categorical risk category defined in § 424.518(c) because we acknowledge that MDPP may bring organization types that are entirely new to Medicare. We also believe that MDPP suppliers have some similarities to home health agencies because non-medical personnel may deliver MDPP services in a non-clinical setting, such as at Y–USA. We seek comments on this approach.

As suppliers, enrolled MDPP organizations would be obligated to comply with all statutes and regulations that establish generally applicable requirements for Medicare suppliers. For example, there are regulations that specify time limits for filing claims (§ 424.44), requirements to report and return overpayments (§ 401.305), and procedures for suspending, offsetting or recouping Medicare payments in certain situations (§ 405.371).

We propose that before enrolling in Medicare, DPP organizations must have either preliminary or full CDC recognition status. Organizations that

apply for CDC recognition can attain preliminary CDC recognition within 1 year of applying, and full upon demonstrating program effectiveness within 24–36 months of applying. We propose that if an organization loses its CDC recognition status at any point, or withdraws from the CDC recognition program at any point, or fails to move from preliminary to full recognition within 36 months of applying for CDC recognition, the organization would be subject to revocation of its Medicare billing privileges for MDPP services as provided by 42 CFR part 424, subpart P. Under the CDC standards for recognition, an organization that loses its CDC recognition (and thus, under our proposal, would no longer be able to bill Medicare for MDPP services) must wait 12 months before reapplying for recognition. We propose that DPP organizations would be eligible to re-enroll in Medicare as an MDPP supplier if, after reapplying for CDC recognition, the organization again achieves preliminary recognition. CDC's standards for recognition as a DPP organization can be found at <http://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf>.

We propose to permit CDC-recognized organizations who are not already enrolled in Medicare (on the basis of being an existing Medicare provider or supplier) to apply to enroll any time on or after January 1, 2017. Existing Medicare providers and suppliers that wish to bill for MDPP services would have to inform us of that intention and satisfy all other requirements, but would not need to enroll a second time. These existing Medicare providers and suppliers would be eligible to bill for MDPP services furnished on or after January 1, 2018. We also considered an alternative approach where existing Medicare providers and suppliers would have to submit a separate enrollment application (including any applicable enrollment application fee) and be separately screened to be eligible to bill for MDPP services. We seek comments on our approach.

Requirements for MDPP Coaches: We propose to require personnel who would deliver MDPP services, referred to hereafter as “coaches”, to obtain a National Provider Identifier (NPI) to help ensure the coaches meet CMS program integrity standards. We are also considering requiring that coaches enroll in the Medicare program in addition to obtaining an NPI, and we seek comment on this approach. An alternative policy we considered was to require DPP organizations to collect and submit to Medicare information on the coaches who would deliver MDPP

services, which could include identifying information such as first and last name and social security number. However, we determined that doing so would require CMS implement a new process, rather than leveraging an existing process, and increase CMS use of social security numbers as a primary identifier. In addition, by requiring coaches to obtain NPIs, we align with current process for provider enrollment and program integrity efforts. We propose to require MDPP suppliers to submit the active and valid NPIs of all coaches who would furnish MDPP services on behalf of the MDPP supplier as an employee or contractor. If MDPP suppliers fail to provide active and valid NPIs of their coaches, or if the coaches fail to obtain or lose their active and valid NPIs, the MDPP supplier may be subject to compliance action or revocation of MDPP supplier status.

- *Revocation of MDPP billing privileges:*

We propose that all MDPP suppliers would be required to comply with the requirements of 42 CFR part 424. If an MDPP supplier has its Medicare enrollment revoked or deactivated for reasons independent of DPRP recognition, that supplier would lose its ability to bill Medicare for MDPP services but would not automatically lose its DPRP recognition from the CDC. We propose that existing Medicare providers and suppliers who lose CDC recognition would lose their Medicare billing privileges with respect to MDPP services, but may continue to bill for other non-MDPP Medicare services for which they are eligible to bill. We propose that MDPP Suppliers that have their Medicare billing privileges revoked or that lose billing privileges for MDPP may appeal these decisions in accordance with the procedures specified in 42 CFR part 405, subpart H, 42 CFR part 424, and 42 CFR part 498. We propose to add a new § 424.59 to our regulations to specify the suppliers who would be eligible for Medicare enrollment and billing for MDPP services. We seek comment on this proposal.

- *Expected MDPP Reimbursement:*

Expected MDPP Reimbursement Structure: We plan to reimburse for MDPP services at the times and in the amounts set forth in the Table 35, with payment tied to number of sessions attended and achievement of a minimum weight loss of 5 percent of baseline weight (body weight recorded during the beneficiary's first core session). MDPP suppliers would be required to attest to beneficiary session attendance and weight loss at the time claims are submitted to Medicare for payment. Each beneficiary's attendance

must be documented through paper or electronic means and that each beneficiary’s weight must be measured and recorded every MDPP session the

beneficiary attends. MDPP suppliers would be required to securely maintain beneficiary attendance records and measured weights and make them

available to CMS or its designee for audit at any time.

TABLE 35—DPP PAYMENT MODEL

	Payment per beneficiary (non-cumulative)
Core Sessions	
1 session attended	\$25
4 sessions attended	50
9 sessions attended	100
Achievement of minimum weight loss of 5% from baseline weight	160
Achievement of advanced weight loss of 9% from baseline weight	* 25
Maximum Total for Core sessions	360
Maintenance Sessions (Maximum of 6 monthly sessions over 6 months in Year 1)	
3 Maintenance sessions attended (with maintenance of minimum required weight loss from baseline)	45
6 Maintenance sessions attended (with maintenance of minimum required weight loss from baseline)	45
Maximum Total for Maintenance sessions	90
Maximum Total for first year	450
Maintenance Sessions After Year 1 (Minimum of 3 sessions attended per quarter/no maximum)	
3 Maintenance sessions attended plus maintenance of minimum required weight loss from baseline	45
6 Maintenance sessions attended plus maintenance of minimum required weight loss from baseline	45
9 Maintenance sessions attended plus maintenance of minimum required weight loss from baseline	45
12 Maintenance sessions attended plus maintenance of minimum required weight loss from baseline	45
Maximum Total After First Year	180

* In addition to \$160 above.

Submission of Claims for MDPP Services: As Table 35 illustrates, proposed payments would be heavily weighted toward achievement of weight loss over the first 6 months, and no payments would be available after the first 6 months without achievement of the minimum weight loss. In the proposed payment structure, claims for payment would be submitted following the achievement of core session attendance, minimum weight loss, maintenance session attendance, and maintenance of minimum weight loss. For example, MDPP suppliers would not be able to submit another claim after session one until the beneficiary has completed four sessions, and maintenance sessions would not qualify for payment unless minimum weight loss is achieved and maintained. Similar value-based payments are being offered by commercial insurers and accepted by DPP organizations. We seek comment on this payment structure. We seek comment on whether to update payment rates annually through an existing fee schedule, such as the PFS, or establish a new fee schedule for MDPP suppliers.

• *IT infrastructure and capabilities:* We propose that in order to receive payment, MDPP suppliers would be required to submit claims to Medicare using standard claims forms and procedures. Claims would be submitted in batches that contain beneficiary Protected Health Information (PHI) and Personally Identifiable Information (PII), including the Health Insurance Claim Number (HICN). Most Medicare claims are submitted electronically except in limited situations. We provide a free software package called PC-ACE Pro32 that creates a patient database and allows organizations to electronically submit claims to Medicare Part A and B. We understand there are several other electronic claims submissions software packages available in the market for purchase. We encourage current and prospective DPP organizations to investigate adopting these systems to enhance the efficiency of claims submission, and we seek comment on the capacity of DPP organizations to integrate these systems into their workflows. If this provision is finalized, we would provide technical assistance to MDPP suppliers to comply with the

Medicare claims submission standards. We seek comment from current and prospective DPP organizations on their ability to transmit claims to Medicare in a timely and secure manner.

We propose to require MDPP suppliers to maintain a crosswalk between the beneficiary identifiers they submit to CMS for billing purposes and the beneficiary identifiers they provide CDC for the beneficiary level-clinical data. We propose that MDPP suppliers provide this crosswalk to the CMS evaluator on a regular basis. We seek comment on this approach.

We plan to propose to require MDPP suppliers to maintain records that document the MDPP services provided to beneficiaries. We propose that these records must contain detailed documentation of the services provided, including but not limited to the beneficiary’s eligibility status, sessions attended, the coach furnishing the session attended, the date and place of service of sessions attended, and weight. MDPP suppliers would be required to maintain these records within a larger medical record, or within a medical record that an MDPP supplier

establishes for the purposes of administering MDPP. Consistent with the requirement in § 424.516(f) we propose that these records be retained for 7 years from the date of service and that MDPP suppliers would provide CMS or a Medicare contractor access to these records upon request. We propose to require MDPP suppliers to accurately track payments and resolve any discrepancies between claims and the beneficiary record within their medical record. We also propose that MDPP suppliers would be required to maintain and handle any beneficiary PII and PHI in compliance with HIPAA, other applicable privacy laws and CMS standards. If this provision is finalized, we intend to provide education and technical assistance to DPP organizations to mitigate the risk of data discrepancies and audits. We seek comment on our approach. We would address specific recordkeeping requirements and standards in future rulemaking.

- *MDPP Eligible beneficiaries:* We propose that coverage of MDPP services would be available for beneficiaries who meet the following criteria: (1) Are enrolled in Medicare Part B; (2) 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 and a BMI of at least 23 if self-identified as Asian. The CDC standards have defined a lower BMI for Asian individuals based on data that show Asians develop abnormal glucose levels at a lower BMI; (3) 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, or a fasting plasma glucose of 110–125 mg/dL, or a 2-hour post-glucose challenge of 140–199 mg/dL (oral glucose tolerance test). We use this definition of prediabetes instead of the definition in § 410.18 because the 2016 American Diabetes Association Standards of Care includes the use of a hemoglobin A1c test to diagnose prediabetes and the CMS actuarial certification uses the World Health Organization definition of prediabetes as a fasting plasma glucose of 110–125 mg/dL; (4) have no previous diagnosis of Type 1 or Type 2 diabetes. A beneficiary with previous diagnosis of gestational diabetes is eligible for MDPP; and (5) does not have end-stage renal disease (ESRD).

The National DPP currently allows community-referral such as by Y–USA and self-referral of patients, in addition to referral by physicians and other health care practitioners, if the patient presents DPP-qualifying blood test results that the DPP organization keeps on record. We propose to similarly

permit beneficiaries who meet the proposed criteria above to obtain MDPP services by self-referral, community-referral, or health care practitioner-referral.

We propose to establish the beneficiary eligibility criteria at § 410.79. We seek comment on this proposal.

- *Program integrity:* We propose all DPP organizations that are eligible and wish to bill Medicare would enroll as MDPP suppliers, and thus would be required to comply with applicable Medicare supplier enrollment, program integrity, and payment rules. We recognize the potential for fraud and abuse by filing inaccurate claims and/or duplicative claims on beneficiaries' sessions attended or weight loss achieved. We also recognize beneficiaries may move between MDPP suppliers, and we intend to address in future rulemaking requirements to prevent duplication of a beneficiary's claims for the same services by more than one MDPP supplier. We are also concerned about the potential for beneficiary inducement or coercion and the potential program risks posed by permitting a new type of organization to receive payment from CMS for providing MDPP services. We intend to develop policies, and will propose them in future rulemaking, to mitigate these risks, and monitor the MDPP expansion to ensure MDPP suppliers meet all applicable CMS program integrity and supplier enrollment standards. We intend to develop system checks to identify where CMS may need to audit an MDPP supplier's medical records. We are considering ways CMS could cross reference the data DPP organizations are currently required to report to the CDC to identify potential discrepancies with data submitted to us. We seek comment on such approaches. Finally, MDPP suppliers would be subject to audits and reviews performed by CMS program integrity and/or review or audit contractors in addition to program-specific audits. We seek comment on these approaches and others to mitigate these risks and strategies to ensure program integrity.

- *Site of service:* Currently, CDC-recognized DPP organizations deliver DPP services in-person or virtually via a telecommunications system or other remote technology. The majority of current DPP organizations provide DPP services in-person, but an emerging body of literature supports the effectiveness of virtual sessions delivered remotely. We propose to allow MDPP suppliers to provide MDPP services via remote technologies. As part of our evaluation of the MDPP

expansion, to the extent feasible, we will evaluate the effectiveness of MDPP services, particularly in relation to virtual versus in-person services, and, using the evaluation data, may modify or terminate this component of the expansion as appropriate. To permit such evaluation, we are considering specifying the nature of the virtual service and the site of the service in codes included on claims submitted for payment, as well as collecting information on the nature of the virtual service and the site of service at the beneficiary level from MDPP suppliers. We seek comment on this approach. Under this last example, MDPP suppliers would be expected to maintain this information as part of the beneficiary level cross walk discussed under the IT Infrastructure and Capabilities section of this proposed rule.

We plan to monitor administrative claims for virtual services to identify any unusual and/or adverse utilization of the DPP benefit. We seek comment on specific monitoring activities or program integrity safeguards with respect to virtual services, in addition to the time period in which such enhanced monitoring activities should occur.

We note that MDPP services provided via a telecommunications system or other remote technology will not be part of the current Medicare telehealth benefits and have no impact on how telehealth services are defined by Medicare. We recognize that the provision of MDPP services by such virtual methods may introduce additional risks for fraud and abuse, and if this proposal is finalized, we would propose specific policies in future rulemaking to mitigate these risks. We thus seek comment on whether there are quality or program integrity concerns regarding the use of virtual sessions, or whether they offer comparable or higher quality MDPP services when compared to in-person services. We seek comment on strategies to strengthen program integrity and minimize the potential for fraud and abuse in virtual sessions.

- *Learning activities:* The CDC provides technical assistance to DPP organizations recognized by the DPRP to improve performance. We intend to coordinate with CDC to supplement this technical assistance with education, training and technical assistance on data security, claims submission and medical record keeping. We seek comment on what additional technical assistance would be needed by providers and other organizations in order to expand the MDPP model.

- *Quality monitoring and reporting:* We seek comment on the quality metrics

that should be reported by MDPP suppliers in addition to the reporting elements required on Medicare claims submissions outlined above (attendance and weight loss) or by the CDC recognition program. We seek comment specifically on what quality metrics should be considered for public reporting (not for payment) to guide beneficiary choice of MDPP suppliers.

- *Timing of the MDPP expansion:* Expanding the MDPP model will be a technically and logistically complex undertaking. One option may be to expand the MDPP nationally in its first year of implementation. Another option is a “phase-in” approach, where the MDPP is expanded initially for a period of time in certain geographic markets or regions, or is furnished by a subpopulation of MDPP suppliers, with the goal of addressing technical issues prior to broader expansion. We seek comment on expanding DPP nationally, and specifically on what factors we should consider in the selection of initial MDPP suppliers.

K. Medicare Shared Savings Program

Under section 1899 of the Act, we established the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in health care costs. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Shared Savings Program: Accountable Care Organizations Final Rule (76 FR 67802) (November 2011 final rule)). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Shared Savings Program; Accountable Care Organizations Final Rule (80 FR 32692) (June 2015 final rule)). A final rule addressing changes related to the program’s financial benchmark methodology appeared in the June 10, 2016 **Federal Register** (Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebased Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations (81 FR 37950) (June 2016 final rule)). As noted below, we have also made use of the annual PFS rules

to address quality reporting and certain other issues.

Additionally, on April 27, 2016, the Department of Health and Human Services (HHS) issued a proposed rule to implement key provisions of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and establish a new Quality Payment Program (QPP) (Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (81 FR 28162) (QPP proposed rule)). The QPP proposed rule would establish a new program under which Medicare would reward physicians for providing high-quality care, instead of paying them only for the number of tests or procedures provided. The QPP proposed rule addresses issues related to APMs, such as the Medicare Shared Savings Program, and issues related to reporting for purposes of MIPS by eligible clinicians (ECs) that are participating in APMs.

Our intent in this proposed rule is to propose further refinements to the Shared Savings Program rules, and we have identified several policies that we propose to update or revise. First, we discuss and propose policies related to ACO quality reporting including proposing changes to the quality measures used to assess ACO quality performance, changes in the methodology used in our quality validation audits and the way in which the results of these audits may affect an ACO’s sharing rate, various issues related to alignment with policies proposed in the QPP proposed rule, and revisions related to the terminology used in quality assessment such as “quality performance standard” and “minimum attainment level.” We are also proposing conforming changes to our regulatory text. Next, we address several issues unrelated to quality reporting and assessment. Specifically, we propose to implement a process by which beneficiaries may voluntarily align with an ACO by designating an ACO professional as responsible for their overall care. We also propose to introduce beneficiary protections related to use of the SNF 3-Day Waiver. Finally, we are proposing to make technical changes to certain rules related to merged and acquired TINs and the minimum savings rate (MSR) and minimum loss rate (MLR) that would be used during financial reconciliation for ACOs that fall below 5,000 assigned beneficiaries.

1. ACO Quality Reporting

Section 1899(b)(3)(A) of the Act requires the Secretary to determine appropriate measures to assess the quality of care furnished by ACOs, such as measures of clinical processes and outcomes; patient, and, wherever practicable, caregiver experience of care; and utilization such as rates of hospital admission for ambulatory sensitive conditions. Section 1899(b)(3)(B) of the Act requires ACOs to submit data in a form and manner specified by the Secretary on measures that the Secretary determines necessary for ACOs to report to evaluate the quality of care furnished by ACOs. Section 1899(b)(3)(C) of the Act requires the Secretary to establish quality performance standards to assess the quality of care furnished by ACOs, and to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for the purposes of assessing the quality of care. Additionally, section 1899(b)(3)(D) of the Act gives the Secretary authority to incorporate reporting requirements and incentive payments related to the PQRS, EHR Incentive Program and other similar initiatives under section 1848 of the Act. Finally, section 1899(d)(1)(A) of the Act states that an ACO is eligible to receive payment for shared savings, if they are generated, only after meeting the quality performance standards established by the Secretary.

In the November 2011 final rule and recent CY PFS final rules with comment period (77 FR 69301 through 69304; 78 FR 74757 through 74764; 79 FR 67907 through 67931; and 80 FR 71263 through 712710), we have established the quality performance standard that ACOs must meet to be eligible to share in savings that are generated. For example, in the CY 2015 PFS final rule with comment period, we made a number of updates to the quality requirements within the program, such as updates to the quality measure set, the addition of a quality improvement reward, and the establishment of benchmarks for 2 years. We made further updates to the quality measure set, established policies to address outdated measures, and made conforming changes to align with PQRS in the CY 2016 PFS final rule with comment period. Through these previous rulemakings, we have worked to improve the alignment of quality performance measures, submission methods, and incentives under the Shared Savings Program and PQRS. Currently, eligible professionals billing through the TIN of an ACO participant may avoid the downward PQRS