Physician-Focused Payment Model Technical Advisory Committee

Preliminary Review Team Report to the Physician-Focused Payment Model Technical Advisory Committee (PTAC)

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In accordance with the Physician-Focused Payment Model Technical Advisory Committee's (PTAC's) Proposal Review Process described in *Physician-Focused Payment Models: PTAC Proposal Submission Instructions* (available on the PTAC <u>website</u>), physician-focused payment models (PFPMs) that contain the information requested by PTAC's *Proposal Submission Instructions* will be assigned to a Preliminary Review Team (PRT). The PRT will draft a report containing findings regarding the proposal for discussion by the full PTAC. This PRT report is preparatory work for the full PTAC and is not binding on PTAC. This report is provided by the PRT to the full Committee for the proposal identified below.

A. Proposal Information

- 1. Proposal Name: A Single Bundled Payment for Comprehensive Low-Risk Maternity and Newborn Care Provided by Independent Midwife-Led Birth Center Practices that Are Clinically Integrated with Physician and Hospital Services.
- 2. Submitting Organization or Individual: Minnesota Birth Center

3. Submitter's Abstract:

"Pregnancy and birth are usually normal when allowed to proceed with support and careful observation, but since there is potential for complications, an obstetrical safety net is required. More than 70% of pregnancies are low-risk. For these mothers the current maternity care model is fragmented and incents more care. Fee for service payment is at the core of this problem. It lowers the quality of care provided and incurs more expense to the payers. Improvement requires a transition to comprehensive bundled payment for the perinatal care episode.

The Minnesota Birth Center has provided excellent clinical outcomes for more than 1000 mother/baby pairs in a comprehensive collaborative model of care since 2012. Care is provided in certified nurse-midwife (CNM)-led independent birth centers located in Minneapolis and St. Paul, Minnesota. If clinically necessary, care is provided in nearby hospitals by the primary midwife and collaborating physicians. Patient satisfaction is very

high and the cost of providing care is less than the current system. However, unsustainable payer reimbursement and regulation have created barriers that prevent further expansion of this model.

This proposal advocates for a single payment for maternity and newborn care provided to low-risk mother/baby pairs. Our hospital clinical partners have agreed to serve as subcontractors by giving us guaranteed public program case rates for mothers and babies who need hospital care for birth. This model meets the criteria for the most advanced APM model #7. The single payment for the perinatal care episode will drive collaboration. Opportunities for benefit include: improved clinical outcomes, more satisfied mothers, and lower cost.

This model will care for cohorts of 250-300 low-risk pregnant mothers per year. The 4-5 member CNM teams will collaborate with consulting obstetrics, pediatric and neonatal physicians. In addition, prenatal education, doulas, and lactation support services are included. The package of care will be available to all payers. This includes Medicare, which annually pays for the care of 15,000 mothers -- 300 per year in Minnesota. We hope that regulations will ultimately be revised to permit this model and others like it, to serve the nearly 2,000,000 mothers per year whose care is covered by Medicaid."

B. Summary of the PRT Review

Criteria Specified by the Secretary (at 42 CFR§414.1465)	PRT Conclusion	Unanimous or Majority Conclusion
1. Scope of Proposed PFPM (High Priority)	Does not meet	Unanimous
2. Quality and Cost (High Priority)	Does not meet	Unanimous
3. Payment Methodology (High Priority)	Does not meet	Unanimous
4. Value over Volume	Does not meet	Unanimous
5. Flexibility	Does not meet	Unanimous
6. Ability to be Evaluated	Does not meet	Unanimous
7. Integration and Care Coordination	Does not meet	Unanimous
8. Patient Choice	Meets Criterion	Unanimous
9. Patient Safety	Does not meet	Unanimous
10. Health Information Technology	Does not meet	Unanimous

C. PRT Process

The proposal, "A Single Bundled Payment for Comprehensive Low-Risk Maternity and Newborn Care Provided by Independent Midwife-Led Birth Center Practices that Are Clinically Integrated with Physician and Hospital Services" (available on the PTAC website) was received by PTAC on July 20, 2017. The PRT conducted its work between August 17, 2017 and November 1, 2017. During this time, the PRT reviewed the proposal, all public comment letters received on the proposal, and additional data and information on the number and characteristics of births paid for by the Medicare program. The PRT also sought clinical consultation from an obstetrician on the services to be included in the bundled payment and on the clinical criteria to be used to exclude women from this bundled payment program.

The PRT's summary of the proposal and description of the other data and information reviewed by the PRT are below. The proposal, additional data and information reviewed by the PRT, and all letters received from the public are available at the PTAC website.

1. Proposal Summary:

As well described by its title, A Single Bundled Payment for Comprehensive Low-Risk Maternity and Newborn Care Provided by Independent Midwife-Led Birth Center Practices that Are Clinically Integrated with Physician and Hospital Services, this submitted model proposes bundled payments for Iow-risk pregnancies for the maternity and newborn care period, which the proposal refers to as the "perinatal episode." This proposal defines the "perinatal episode" as nine months of pregnancy plus eight weeks postpartum for the mother, and newborn care for the first 24 hours of life. The proposed model would cover the episode from initiation of prenatal care through eight weeks postpartum for the mother and through the 24-hour newborn period for the newborn. The proposal states that the definition of "low-risk" is "largely based on the absence of high risk factors," and identifies 35 "Exclusionary Risk Criteria" for this model. Certified nurse midwives (CNMs) would be the primary providers to patients; the proposal states, "our model is most accurately described as a 'Provider Focused Payment Model' with integral physician involvement."

The proposal presents background information on mothers' preference for low-intervention birth; highlighting a 2012 national survey finding that nearly 60% of mothers believe that birth is a normal process that should not be interfered with unless medically necessary. Information also was reported on the experiences of mothers with *low-risk* pregnancies, including that low-risk women who have midwife-directed care in a freestanding birth center receive excellent care at a lower cost and fewer cesarean sections and operative vaginal births without increasing adverse perinatal outcomes.

The proposed bundle would include all professional and facility fees during labor and birth, which the submitter has experience with and refers to as the BirthBundle®. The list of CPT codes and services within the BirthBundle® are specified in the proposal; these include mother professional fees, newborn professional fees, prenatal lab tests, and facility fees.

The submitted PFPM proposes to care for cohorts of 250–300 low-risk pregnant mothers per year through the use of five-member CNM teams collaborating with consulting obstetric, pediatric, and neonatal physicians. The CNM team has hospital privileges, so when mothers or babies require more than the birth center level of care, care is available in the hospital. If physician services are required, these also are available 24/7 in the hospital. In addition, prenatal education, doulas, and lactation support services are included in the package of care, which would be available to all payers, including Medicare. The proposal requests approval and expansion of the BirthBundle® and similar comprehensive perinatal care and bundled payment models throughout the country (emphasis added).

2. Additional Information Reviewed by the PRT.

a) Environmental Scan and Literature Review

ASPE, through its contractor, conducted an abbreviated environmental scan related to this proposal. Documents comprising the environmental scan were primarily identified using Google and PubMed search engines. Key words guiding the environmental scan and literature review were directly identified from the Letter of Intent (LOI). The key words and combination of key words were utilized to identify documents and material regarding the submitting organization, the proposed model in the LOI, features of the proposed model in the LOI, or subject matter identified in the LOI. Key terms used included "maternal bundled payment," "maternity care," "maternity care model," "maternity episode of care," "maternal health payment reform," "Minnesota Birth Center," "newborn care," and "single bundled payment." This search produced five documents from the gray literature and four peer-reviewed articles. These documents are not intended to be comprehensive and are limited to documents that meet predetermined research parameters including a five-year look back period, a primary focus on U.S. based literature and documents, and relevancy to the LOI.

b) Data Analyses

The PRT sought additional information regarding the annual number of Medicare-covered pregnancies and their characteristics. The Office of the Assistant Secretary for Planning and Evaluation (ASPE), through its contractor, produced data tables containing this information that are available on the PTAC website.

D. Evaluation of Proposal Against Criteria

Criterion 1. Scope of Proposed PFPM (High Priority Criterion). Aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited.

PRT Qualitative Rating: Does not meet

While the PRT found the concept of a bundled payment for perinatal care to be a worthy concept for insurers that cover a large number of deliveries and newborns, it did not find the proposed model to be equally applicable as a physician-focused payment model (PFPM) for the Medicare program. This is primarily because of the very low volume of Medicare-covered pregnancies overall — and high unlikelihood of Low-risk Medicare pregnancies in particular. The proposal states, "Perinatal care is a major spending area for commercial insurance and for Medicaid," and "Seven of the 20 most expensive hospital conditions are related to pregnancy, labor and birth and these costs account for 27% of all Medicaid spending. Perinatal care is the most costly condition for employers who provide health insurance benefits, and accounts for 15% of costs for commercial insurers." However, the same is not said for Medicare.

The PRT's commissioned analysis of Medicare data found only 22,086 Medicare-covered births nationwide in 2016. 73.9% of these were identified as having one or more co-occurring chronic conditions. Although this data found a small number (26.1 %) or 5,764 pregnancies covered by Medicare "without complications," even this small number is suspect because of the widely acknowledged incompleteness of medical coding and because the only way for a woman of childbearing age to be eligible for Medicare coverage would be through the presence of a disability, End Stage Renal Disease, or other serious disease — which would decrease the likelihood of such a pregnancy being "low risk."

Additionally, the probable low number of low-risk Medicare births would prevent fair assumption of risk-based payment, quality measurement, and the model's ability to be evaluated in the Medicare program.

Further, this proposal would include coverage of newborn care for the first 24 hours of life. However, the Medicare benefit package does not include newborn care based on a mother's eligibility. After the infant is delivered, items and services furnished to the infant are not covered and reimbursed under the program on the basis of the mother's eligibility.

The PRT concluded that the Medicare program is not the right vehicle for the development and testing of this model, and could not find that the proposed model would likely directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited. The PRT thought that commercial payers and State Medicaid programs would be more appropriate venues for the further development of this worthy concept.

Criterion 2. Quality and Cost (High Priority Criterion). Are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

PRT Qualitative Rating: Does not meet

The proposal states on page 6 that, "There are significant variations in the quality and cost of perinatal care throughout the US and within states. Varying cesarean section rates and costs are the major factor." Consistent with this, Section III of the proposal addressing this Quality and Cost criterion discussed only C-section rates, and did not identify other measures of health care quality to be used. However, a public comment letter submitted by the American Association of Birth Centers identified quality measures for maternity care as: number of prenatal visits, cesarean birth rate, elective delivery before 39 weeks, preterm birth and low birth weight rates, breastfeeding initiation and continuation, NICU admissions, readmissions, perineal integrity, and completion of the 6-week postpartum visit as measures of perinatal quality. Although the proposal did state that accreditation by the Commission for Accreditation of Birth Centers should be mandatory for participation in bundled perinatal payments, the PRT found the absence of comprehensive quality measures as a risk to improving or maintaining quality.

With respect to the payment model controlling costs, the proposal states that cost savings are expected to be realized "through a lower-intervention model of maternity care that is highly-coordinated and leverages the use of a birth center, a lower-cost facility." The PRT did not view a cost differential resulting from change in the site-of-care by itself as a payment model change.

Criterion 3. Payment Methodology (High Priority Criterion). Pay APM Entities with a payment methodology designed to achieve the goals of the PFPM criteria. Addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the Physician-Focused Payment Model cannot be tested under current payment methodologies.

PRT Qualitative Rating: Does not meet

The proposed model calls for the use of a bundled payment for the costs of individual perinatal episodes, but beyond identifying the concept of bundled payment, a payment methodology is not further described in the proposal. For example, the proposal states:

"We would appreciate PTAC assistance in further design of the payment methodology for this PFPM. This would include help in determining the appropriate amount of the bundled payment as well as the timing of its distribution. In addition, we would like to explore the possibility of having providers take on additional risk beyond the single bundled payment. Finally, stop loss insurance or risk pools will be needed for the rare expensive outlier perinatal cases. . . .

Providers should not have to carry the costs of care for many months after performing the service. A solution would be an upfront partial payment at 20 weeks gestation

followed by a final retrospective bundled payment shortly after completion of the episode. Providers could also take on additional risk by taking cost responsibility for some multiple of the agreed upon bundled price. It would be very helpful to have PTAC assistance in addressing these questions."

The proposal also states that, "a specific pregnancy insurance component could provide outlier payment adjustments if the costs for a patient or her baby exceeded a certain amount. This would reduce the financial risk to providers and facilities participating in the bundled payment program." However, this concept is not further detailed in the proposal.

As a result, the PRT concluded that the submission did not sufficiently describe a payment methodology such that the PRT could find that the proposed model, "Addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the Physician-Focused Payment Model cannot be tested under current payment methodologies."

Criterion 4. Value over Volume. Provide incentives to practitioners to deliver high-quality health care.

PRT Qualitative Rating: Does not meet

The proposal states that the primary volume problem in perinatal care is the overuse of cesarean section, and overuse of ultrasound imaging as another major driver of perinatal care cost. This model proposes to address this issue via the financial incentives inherent in bundled payment to shift from encouraging use of technology-intensive care to encouraging the use of low-technology, high-value approaches. The proposal states that the savings derived from fewer cesarean sections and lower facility fees for the majority of women would offset the costs associated with the small number of complicated births that would require hospital care.

However, because as discussed under Criterion 3. Payment Methodology, the actual payment methodology is not sufficiently described; and as discussed under Criterion 2. Quality and Cost, there is a lack of sufficient measures of health care quality to be used in the model, the PRT could not find that the model would provide incentives to practitioners to deliver high-quality health care.

Criterion 5. Flexibility. Provide the flexibility needed for practitioners to deliver high-quality health care.

PRT Qualitative Rating: Does not meet

The proposal states that "by paying a single amount for the entire perinatal episode providers will have the flexibility to be creative and to use proven high value supportive services to improve outcomes and patient satisfaction." The PRT agrees with this statement in principle, but as discussed in the preceding criteria, the details of this proposed model are not sufficiently developed to assume with reasonable certainty that it will provide the flexibility needed for practitioners to deliver high-quality health care. The PRT does not believe that one can automatically assume delivery of high-quality care based solely on the use of a bundled payment.

Criterion 6. Ability to be Evaluated. Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

PRT Qualitative Rating: Does not meet

Because: 1) Medicare is not a major payer of perinatal care, 2) only a very small number of Medicare beneficiaries could likely be included in a model of care for low-risk beneficiaries, and 3) variation in State laws affect scope of practice and subsequently the design of the model, the PRT believes it would be very difficult to evaluate this proposed model in the Medicare program. In addition, as described in Criterion 2, above, specific evaluable goals for quality of care were not sufficiently articulated in the proposal.

Criterion 7. Integration and Care Coordination. Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

PRT Qualitative Rating: Does not meet

With respect to this criterion, the proposal states in full:

"This care model is based on integrated CNM-led multispecialty teams caring for cohorts of 250-300 mother/baby pairs each year. Having 4 or 5 CMN FTEs on each team maximizes continuity of care for the mothers with avoidance of burnout for the CNM providers.

Care coordination is crucial. We utilize the unique and the overlapping skills of CNMs, RNs, LPNs, perinatal educators, doulas and administrative personnel to provide a caring and consistent care path for mothers. This works well for mothers without complications, but it also works well when complications develop.

In tragic situations when lethal fetal abnormalities are detected, many mothers choose perinatal hospice care. This involves providing clinical and emotional support for a mother and family as they await the natural birth and death of their child. Our model

has provided support for families in this situation, as well as those with other complications."

As discussed in the preceding criteria, the details of how this model will encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population are not sufficiently described. For example, the composition of the CNM-led multispecialty teams and the clinical integration with physicians and hospitals are not well described. Further, the PRT notes that no measures of care coordination are proposed.

As with Criterion 5, The PRT does not believe that one can automatically assume greater integration and care coordination among practitioners and across settings based solely on the use of a bundled payment.

Criterion 8. Patient Choice. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

PRT Qualitative Rating: Meets Criterion

Because the proposed model would offer mothers the services of perinatal educators and doulas, along with the services of CNMs, RNs, LPNs, and physicians and choice of setting for delivery, the PRT believes that patients would have greater choice of service providers and setting of care. This would encourage greater attention to the choices of individual patients.

Criterion 9. Patient Safety. Aim to maintain or improve standards of patient safety.

PRT Qualitative Rating: Does not meet

The PRT was not able to conclude that this proposed model meets this criterion. The main reasons for this are twofold. First, the proposed model defines "low risk" pregnancies as those that do not have certain maternal conditions (i.e., "exclusion criteria") that are specified in the proposal. No explanation is given for how these exclusion criteria were determined. A PRT-commissioned review of the exclusion criteria by an obstetrical consultant identified several other maternal (and fetal) conditions recommended as exclusionary criteria. Further, comments received on this proposal from the Minnesota State Chapter of the National Association of Certified Professional Midwives (NACPM), the Washington State Chapter of NACPM and the Minnesota Council of Certified Professional Midwives state:

"It is important to note that the risk criteria submitted is for the author's practice. Birth centers accredited by the Commission for the Accreditation of Birth Centers (CABC) follow a different set of risk criteria as determined by the American Association of Birth

Centers (AABC). This risk assessment is based on a multi-disciplinary group of CPMs, CNMs, and physicians in a review of current evidence."

The proposal states that, "Our PFPM is designed to maximize the number of mothers and babies cared for within the bundled clinical care and payment model." The PRT was concerned that the proposed exclusionary criteria might indeed maximize the number of mothers included in the bundled payment model but as a side effect might not afford sufficient protection to beneficiaries.

Further, although the proposal states that accreditation by the Commission for Accreditation of Birth Centers should be mandatory for participation in bundled perinatal payments, the PRT believes accreditation is currently required by most state laws. The PRT expected to see additional patient safety standard for this proposed new payment, especially as without strong quality measures (as discussed in the PRT's comments under Criterion 2. Quality and Cost) a bundled payment approach could incentivize stinting on care. Such patient safety standards could include, for example, a quality improvement process with case review to ensure appropriate care (and testing) is being provided, and systematic tracking of patient (mother and baby) outcomes.

Criterion 10. Health Information Technology. Encourage use of health information technology to inform care.

PRT Qualitative Rating: Does not meet

Under this criterion, this proposal stated in full:

"Health information technology tools can help mothers wisely choose their preferred care model and to access care through that model. The integrative nature of our perinatal care PFPM provides an excellent foundation for the development of these tools.

Health information technology can also be applied to the vast amount of coding and billing data that is crucial for the analysis and definition of bundled payments. Our model necessarily started at a grassroots level, but other tools have been developed. These include the PROMETHEUS model of the Health Care Incentives Improvement Institute (HCI3). The combination of these complex tools with grassroots clinical bundle initiatives such as ours can assist with perinatal care improvement."

The PRT found these two paragraphs insufficiently describe how this model would use or encourage use of health information technology to inform care. The PRT was looking for some level of specificity about how health information technology would be used in this model.

E. PRT Comments

While the PRT appreciated the potential for bundled payments of perinatal care to provide improvements in patient choice, quality and costs, it was chagrined in that the Medicare program is not the best vehicle for testing such a bundled payment model — and by extension that PTAC is not the best vehicle for responding to such a proposal. The PRT notes that the submitted proposal seems to reflect this perspective as well, in its repeated references to Medicaid, including:

"The ultimate goal is to provide higher value perinatal care for a lower price for mothers covered by Medicaid. When this is achieved it will encourage bundled payment for mothers covered by commercial insurance."

While the PRT concluded that this proposal does not meet key criteria for physician-focused payment models in the Medicare program, it hopes that well-developed proposals for the use of bundled payment for perinatal care can and will be considered by the federal and State Medicaid programs and commercial insurers.

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