



June 30, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-9942-NC
PO Box 8016
Baltimore, MD 21244-8016

RE: CMS-1607-P: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long- Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program

Dear Ms. Tavenner:

The Coalition for Quality Maternity Care (CQMC), a group of national professional, consumer, and human rights organizations that promote high quality maternity care for all women and newborns is pleased to submit the following comments regarding the “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long- Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program” published in the *Federal Register* on May 15, 2014.¹ We hope that you find our comments helpful and look forward to your response in the final rule.

¹ 79 FR 27978

COMMENTS

For the reasons outlined below, the CQMC supports CMS' proposals with regard to the following four quality measures.

IV.I.4.c.(3) - PC-01: Elective Delivery Prior to 39 Completed Weeks Gestation (NQF #0469)

Proposal: Under this heading, CMS proposes to include the "PC-01: Elective Delivery Prior to 39 Completed Weeks Gestation" quality measure in the Hospital Value Based Payment Program (HVBP) for FY 2017.

Recommendation: We strongly support CMS' proposal to include this measure within the HVBP program, and urge the agency to do so at the earliest possible date.

Justification: The recent inclusion of this measure within the Hospital Inpatient Quality Reporting (IQR) program, reporting requirements by the Joint Commission, and concerted efforts by Medicaid programs, commercial insurers and many hospitals across the country have recently resulted in significant declines in the rate of early elective delivery. However, as CMS' own IQR data show, there are still significant regional variations and variations among hospitals within the same geography. Many hospitals continue to have rates of early elective delivery in excess of 15 percent. Others have failed to report the measure as required.

For decades the American College of Obstetricians and Gynecologists (ACOG) has recommended that no elective delivery be performed before the gestational age of 39 weeks without a medical indication. Nonetheless, the practice continues. Early elective deliveries are tied to increased rates of late-preterm births, increased neonatal morbidity, neonatal intensive care unit admissions, and associated hospital costs compared to deliveries occurring at 39-40 weeks.² Efforts to reduce elective deliveries have been effective.³ CMS has recognized the importance of reducing the rate of early elective deliveries and has developed both the Strong Start for Mothers and Newborns and the Neonatal Outcomes Improvement Project to further that goal.⁴ We believe that CMS can help to promote similar efforts by hospitals that have hitherto failed to sufficiently focus on this issue by including the measure in the HVBP program. Not only will such efforts reduce costs but they also have the potential to greatly improve newborn outcomes of care. Finally, providers have a very clear, direct ability to influence this practice. Those who do so should be recognized.

² D.M. Ashton "Elective Deliveries at Less than 39 Weeks," in *Current Opinion in Obstetrics and Gynecology*, 2010 Dec; 22(6): 506-510.

³ One maternity hospital lowered its NICU admission rate by 50 percent by putting in place mechanisms to control early elective deliveries. See: <http://www.newswise.com/articles/early-elective-deliveries-reduction-halves-nicu-admissions>

⁴ See a CMS paper entitled "Reducing Early Elective Deliveries in Medicaid and CHIP," available at: <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/Downloads/EED-Brief.pdf>

IX.A.7.f.(3) Proposed Voluntary Measure: PC–05: Exclusive Breast Milk Feeding and the Subset Measure PC–05a Exclusive Breast Milk Feeding Considering Mother’s Choice (Collectively Referred to as NQF #0480)

Proposal: Under this heading CMS proposes to include the “PC-05: Exclusive Breast Milk Feeding and the Subset Measure PC-05a Exclusive Breast Milk Feeding Considering Mother’s Choice” quality measure in the IQR program for FY 2017 payment determination.

Recommendation: We strongly support CMS’ proposal to include this measure in the IQR, and urge the agency to do so at the earliest possible date. As many hospitals are currently in the process of adopting, adapting or merging EHR systems, the timing is optimal to encourage hospitals and vendors to come together in order to develop universal procedures for collecting and reporting breastfeeding information. We therefore further recommend the integration of technical assistance provided by The Joint Commission (TJC), the United States Breastfeeding Committee (USBC), and other organizations to ease the transition and develop accurate and uniform processes. The USBC has developed in collaboration with an Expert Panel a set of Guidelines for EHR’s in the implementation of PC-05 and PC-05a. The USBC has also published an on line toolkit to aid hospitals in implementing reporting on TJC PC-05 and PC-05a.⁵ CMS should inform the hospital community regarding the availability of this toolkit to assist them in reporting this measure.

Justification: Breastfeeding has been proven to foster a host of positive outcomes for both mothers and babies, yet many mothers who desire to breastfeed are not fully supported during the period after birth. This initiation period is critical for ongoing successful breastfeeding.

Research has demonstrated positive outcomes for breastfed babies including that they:

- are less likely to suffer from infectious illnesses and their symptoms (e.g., diarrhea, ear infections, respiratory tract infections, meningitis);⁶
- have a lower risk of the two most common inflammatory bowel diseases (Crohn’s disease, ulcerative colitis);⁷
- suffer less often from some forms of cancer (e.g., Hodgkin’s disease, childhood leukemia);⁸
- have a lower risk of juvenile onset diabetes, if they have a family history of the disease and are breastfed exclusively for at least 4 months;⁹
- are significantly protected against asthma and eczema, if at risk for allergic disorders and exclusively breastfed for at least 4 months; and¹⁰

⁵ The toolkit is available at:

<http://www.usbreastfeeding.org/HealthCare/HospitalMaternityCenterPractices/ToolkitImplementingTJCCoreMeasure/tabid/184/Default.aspx>

⁶ Heinig MJ. Host defense benefits of breastfeeding for the infant: effect of breastfeeding duration and exclusivity. *Pediatr Clin North Am*, 2001; 48: 105–123. Uhari M, Matysaari K, Niemela M. A meta-analytic review of the risk factors for acute otitis media. *Clin Infect Dis* 1996; 22: 1079–1083.

⁷ Heinig MJ, Dewey KG. Health advantages of breastfeeding for infants: a critical review. *Nutr Res Rev* 1996; 9: 89–110.

⁸ Davis MK. Review of the evidence for an association between infant feeding and childhood cancer. *In J Cancer Suppl* 1998; 11: 29–33.

⁹ Heinig MJ, Dewey KG. Health advantages of breastfeeding for infants: a critical review.

¹⁰ Gdalevich M, Mimouni D, David M, Mimouni M. Breast-feeding and the onset of atopic dermatitis in childhood: a systematic review and meta-analysis of prospective studies. *J Am Acad Dermatol* 2001; 45:520–527. Gdalevich M, Mimouni D, Mimouni

- may have a lower risk of obesity in childhood and in adolescence.¹¹

For mothers, the impact of breastfeeding is also significant.

- Women who have breastfed are less likely to develop ovarian and premenopausal breast cancers. The more months a woman has spent breastfeeding, the greater the beneficial effect.¹²
- Breastfeeding mothers enjoy a quicker recovery after childbirth, with reduced risk of postpartum bleeding.¹³
- Mothers who breastfeed are more likely to return to their pre-pregnancy weight than mothers who formula feed. Breastfeeding reduces the risk for long-term obesity.¹⁴
- Exclusive breastfeeding may reduce the risk of anemia by delaying the return of the menstrual cycle for 20 to 30 weeks.¹⁵
- Exclusive breastfeeding for the first 6 months postpartum, in the absence of menses, is 98 percent effective in preventing pregnancy.¹⁶
- Breastfeeding mothers are reported to be more confident and less anxious than bottle-feeding mothers.¹⁷

In addition to these positive health related effects, breastfeeding is significantly less costly than alternative forms of feeding. Unfortunately, breastfeeding is never initiated for approximately one quarter of newborns, just over 44 percent are receiving any breast milk at six months and only approximately 15 percent are being exclusively breastfed at six months of age.¹⁸ There is also significant variation by facility type in the encouragement provided for mothers to breastfeed their newborns.¹⁹

Hospitals and professionals who provide maternity care therein are in an excellent position to encourage breastfeeding. These steps could have a significant impact on the health of literally millions of mothers and children. Furthermore, the ACA has mandated coverage for breastfeeding supplies, equipment and counseling making it simpler to encourage women covered under most types of insurance to engage in this critical practice.²⁰

M. Breast-feeding and the risk of bronchial asthma in childhood: a systematic review with meta-analysis of prospective studies. *J Pediatr* 2001; 139: 261–266.

¹¹ Butte NF. The role of breastfeeding in obesity. *Pediatric Clinics of North America* 2001; 48: 189–198. Gillman MW, Rifas-Shiman SL, Camargo CA Jr, Berkey CS, Frazier AL, Rockett HR, Field AE, Colditz GA. Risk of overweight among adolescents who were breastfed as infants. *JAMA* 2001; 285: 2461–2467.

¹² Heinig MJ, Dewey KG. Health advantages of breastfeeding for mothers: a critical review. *Nutr Res Rev* 1997; 10: 35–56. Lobbok MH. Effects of breastfeeding on the mother. *Pediatr Clin North America* 2001; 48: 143–158.

¹³ Heinig MJ, Dewey KG. Health advantages of breastfeeding for mothers: a critical review

¹⁴ Ibid.

¹⁵ Lobbok MH. Effects of breastfeeding on the mother. *Pediatr Clin North America* 2001; 48: 143–158.

¹⁶ Ibid.

¹⁷ Lawrence RA, Lawrence RM. *Breastfeeding: a guide for the medical profession*. 5th edition. Mosby, St. Louis, 1999.

¹⁸ See the CDC’s “Breastfeeding Report Card – 2012, United States” available online at:

<http://www.cdc.gov/breastfeeding/data/reportcard/reportcard2012.htm>

¹⁹ The CDC’s “Maternity Care Practices Survey” data show variation in support for breastfeeding mothers by state, facility type, facility birth size, NICU level and region, available online at: <http://www.cdc.gov/breastfeeding/data/mpinc/results-tables.htm>

²⁰ See guidance issued by HRSA at: <http://www.hrsa.gov/womensguidelines/>

IX.A.7.f.(5) Proposed Voluntary Measure: Healthy Term Newborn (NQF #0716)

Proposal: Under this heading, CMS proposes to include the “Health Term Newborn” quality measure in the IQR program for FY 2017 payment determination.

Recommendation: We support CMS’ proposal to include this measure in the IQR, and urge the agency to do so at the earliest possible date.

Justification: With regards to the Healthy Term Newborn measure, we note that this measure has recently been refined and hope that CMS will swiftly adopt the updated version, entitled Unexpected Newborn Complications. It is our understanding that the revised measure will be considered during the next NQF measure maintenance opportunity.

This measure, as revised, examines the rate of neonatal complications among normal term births excluding cases with conditions present before labor. These include small for date babies and those with any birth defect or other fetal diagnoses. It addresses the primary goal of birth families—to go home with a healthy baby. This measure has been extensively used by both the California Maternal Quality Care Collaborative (CMQCC) (Stanford University, Palo Alto, CA)²¹ and the National Perinatal Information Center (NPIC) (Brown University, Providence, RI) which together report perinatal outcomes for over 700 hospitals covering approximately 25% of US births. The measure has now been utilized over a wide range of hospitals with good reliability. Moreover, this measure typically applies to more than 80 percent of hospital births.

As performance improvement initiatives work to lower Early Elective Deliveries (PC-01) and Low-risk First-birth Cesarean births (PC-02), there is a need to guard against unexpected consequences. Therefore, it is imperative to have a balancing performance measure that reports term baby outcomes. The ideal maternity unit is one with low maternal interventions such as primary cesarean births among low-risk mothers combined with low rates of unexpected term baby complications. Mothers and fathers preparing for birth or anticipating pregnancy will be very interested in identifying hospitals who have struck this balance.

IX.A.8.b. Possible Future Electronic Clinical Quality Measures: PC–02 Cesarean Section NQF #0471

Proposal: Under this heading, CMS proposes to include in the IQR the “PC-02: Cesarean Section” quality measure. CMS describes plans to propose inclusion of this measure in the IQR for discharges beginning on or after October 1, 2016 or for those occurring on or after October 1, 2017, depending on how the regulation to align the IQR and the Medicare EHR Incentive programs is finalized.

Recommendation: We strongly support CMS’ proposal to include this measure in the IQR and recommend doing so at the earliest possible date.

Justification: In 2013, the total cesarean section birth rate in the United States stood at 32.7

²¹ Full details can be found at: <https://www.cmqcc.org/newborn> and

percent, a rate that is 50% higher than it was a decade ago.²² Furthermore, the variation in cesarean section rates between hospitals in the United States is dramatic, with one recent study finding a range from 7.1% to 69.9%.²³ Even when risk-adjusted, the cesarean section rate varies widely among physicians and hospitals.²⁴ The majority of the increase in primary cesarean rate AND the large majority of the variation among hospitals is captured in the measure, Low-risk First-Birth Cesarean rate (PC-02). This measure focuses on the first labor that determines the reproductive future of the mother (i.e., if the first birth is by cesarean, 90% of all future births will be by cesarean; if the first birth is vaginal, 90% of all future births will be vaginal).²⁵ Numerous studies have documented both short and long-term negative outcomes associated with cesarean sections. Short term harms to the mother that increase with the occurrence of cesarean birth include maternal death, emergency hysterectomy, blood clots and stroke, surgical injury, longer hospitalization and more likely rehospitalization, infection, intense and prolonged postpartum pain, poor overall mental health and self-esteem, poor birth experience, poor overall functioning and less early contact with babies. Longer term impacts of cesarean on mothers include chronic pelvic pain and bowel obstruction. Cesareans are associated with reduced fertility, cesarean scar ectopic pregnancy, placenta previa, placenta accrete, placenta abruption, uterine rupture, hemorrhage, low birthweight, preterm birth, and stillbirth. Babies born via cesarean are more likely to experience respiratory problems, surgical injuries, failure to establish breastfeeding, and asthma in childhood and adulthood.²⁶ Clearly, it is not a procedure that should be undertaken lightly or in a seemingly routine manner as it presently occurs in some facilities in this country.

Cesarean sections are significantly more costly than normal vaginal birth. In 2011, hospital facility charges alone (not including professional charges) for an uncomplicated vaginal birth averaged \$10,657. Hospital charges for an uncomplicated cesarean section birth cost were \$17,859 and charges for a cesarean section with complications averaged \$23,923.²⁷ We believe that if CMS begins collecting and reporting these data on a national scale through the IQR and reporting the outcomes through Hospital Compare, consumers will be empowered to make more informed choices and providers will be motivated to take action to lower what is an unacceptable rate of unnecessary, costly and risk-laden major surgery.

CONCLUSION

We thank CMS for the opportunity to comment on these important issues related to maternal and newborn care. Should you have any questions, please feel free to contact Jesse Bushman at jbushman@acnm.org or 240-485-1843.

²² Brady E. Hamilton, PhD, et. al., "Births: Preliminary Data for 2013," National Vital Statistics Report, vol. 63, no. 2, May 29, 2014, available at: http://www.cdc.gov/nchs/data/nvsr/nvsr63/nvsr63_02.pdf

²³ Katy Backes Kozhimannil, Michael R. Law, and Beth A. Virmig, "Cesarean Delivery Rates Vary Tenfold Among US Hospitals; Reducing Variation May Address Quality and Cost issues," in *Health Affairs*, vol. 32, no. 3, March 2013, pp. 527-535.

²⁴ See, for example, risk adjusted c-section data on individual OB/Gyns and hospitals in Virginia, available at www.vhi.org.

²⁵ Elliott Main, MD, et. al., "Cesarean Deliveries, Outcomes, and Opportunities for Change in California: Toward a Public Agenda for Maternity Care Safety and Quality," California Maternal Quality Care Collaborative, December 2011, pp. 40-42.

²⁶ Carol Sakala and Maureen P. Corry, "Evidence-Based Maternity Care: What It Is and What It Can Achieve," Childbirth Connection, Reforming States Group, Milbank Memorial Fund, 2008, p. 44-46. Available at:

<http://www.milbank.org/uploads/documents/0809MaternityCare/0809MaternityCare.html>

²⁷ See: <http://transform.childbirthconnection.org/resources/datacenter/chargeschart/>

SIGNATORIES

American Association of Birth Centers

American College of Nurse-Midwives

Association of Women's Health, Obstetric and Neonatal Nurses

Centering Healthcare Institute

Childbirth Connection: A Program of the National Partnership for Women and Families

March of Dimes

Midwives Alliance of North America

National Association of Certified Professional Midwives

National Women's Health Network

United States Breastfeeding Committee