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Dear Ms. Kelly and Ms. Thompson:

This letter is sent on behalf of the membership of the South Carolina Chapter of the National Association of Certified Professional Midwives ("SC/NACPM"), the new professional association for Certified Professional Midwives ("CPMs") licensed in this State. The purpose of the letter is to request a definitive statement from the S.C. Department of Health and Environmental Control ("DHEC" or "the Department") regarding several positions recently announced by DHEC staff members with respect to the practice of Licensed Midwives ("LMs") and/or the operation of freestanding birth, or birthing centers, the majority of which in this state are owned and operated by LMs.

The first of these is DHEC's recent re-interpretation of the S.C. regulations governing Licensed Midwives that involve Emergency Measures. Specifically, we seek a precise and authoritative statement regarding the required contact between the LM and a physician. It has been our understanding from prior verbal and written statements provided by DHEC staff members that such consultation must be obtained IMMEDIATELY PRIOR to the administration of lifesaving emergency measures. An LM who administers the emergency measure prior to making personal or telephone contact with the consulting physician will be cited for violation of the rule. The timing of the consultation is a new element that differs from DHEC's prior interpretation of this rule; furthermore, various staff members have responded to verbal inquiries regarding the new interpretation of this differing, inconsistent, and often contradictory manners.

Our second question concerns the Department's recently-issued Position Statement prohibiting the LM use of Misoprostol for postpartum hemorrhage by LMs, while the third involves a "Memo" issued to South Carolina birthing centers reinterpreting and changing long-standing rules and permitted practices with respect to Vaginal Birth After Cesarean Section ("VBAC").

All three of these new interpretations directly contradict current regulations as written and previous interpretations of DHEC LM and/or birth center regulations as well as national Practice Standards and

standards of care for CPMs. The aforementioned practice standards include the National Standards for Practice of CPMs, developed and published by our national professional society, NACPM, a copy of which is enclosed, along with the certification standards used by the North American Registry of Midwives (“NARM”), the nationally-recognized organization that certifies CPMs. Each issue is addressed separately, below.

1. EMERGENCY MEASURES

SC NACPM is aware that an attorney has already brought the problems regarding the Emergency Measures issue, including public health and safety issues, to DHEC's attention. In a letter dated May 14, 2015, it was requested that DHEC provide written confirmation of their interpretation of this rule as well as how it will enforce that interpretation. To date, no response has been issued. Then, on June 11, 2015, following a public meeting regarding proposed revised regulations for birthing centers, the Department was unable to resolve controversy surrounding or respond to questions regarding its interpretation of this and other rules.

At the time of that meeting, Nicole Lavallee, President of SC NACPM, had what was termed an “off-the record” conversation with Gwen Thompson regarding the Emergency Measures rules. Ms. Thompson stated that DHEC would deem it acceptable and compliant with the rule if a Licensed Midwife initiated an Emergency Measure under the following conditions:

- a. an assistant contacts the physician while the LM provides the Emergency Measure
- b. in the event that physician consultation is not possible before the necessitation of Emergency Measures, so long as consultation is documented in the client records immediately following the incident.

Ms. Thompson stated that the Department was working on getting “something in writing.” It is an unacceptable violation of due process for a state regulatory agency to make regulatory changes by stating a new interpretation verbally, and then offering extenuating circumstances for waiver of the interpretation, again verbally, with a vague promise of getting “something in writing” at some point in the future. It is a violation of the state Administrative Procedure Act and of our due process rights for DHEC to try to regulate midwifery in this ad hoc manner.

2. POSITION STATEMENT ON MISOPROSTOL

In response to a Freedom of Information request seeking an understanding and verification of DHEC's decision-making process with respect to the position statement that was issued regarding Misoprostol, the Department produced internal emails that revealed the actual motivations behind the statement:

- A. The Department sought to put a Position Statement in place to assist with a then- current Consent Order case.
- B. The Department was acting in reaction to and in retaliation for unsubstantiated allegations (with no evidence whatsoever) from a competitor physician that ONE midwife in “Upstate S.C.” might be using misoprostol to routinely induce labor for pregnant mothers.

No experts in out-of-hospital birth or birth centers were consulted prior to issuing this Position Statement. Furthermore, although the OB task force and Maternal Child Health were referenced as consultants in the

decision process, there is no evidence that either was in fact consulted. On the contrary, the only evidence produced consists of nothing more than a few scattered emails with three individual physicians. In addition, the records contain no evidence of input from experts or documented research on the efficacy of misoprostol for out-of-hospital management of Post- Partum

Hemorrhage. There is no evidentiary basis for the issuance of this Position Statement, and the process for doing so was highly irregular.

3. VAGINAL BIRTH AFTER CESAREAN IN BIRTHING CENTERS

In response to a similar Freedom of Information request regarding a “Memo” against VBAC’s at birthing centers, the record is likewise sparse of evidence:

- a. Existing clear state regulations were changed - by interpretation - without any formal rulemaking proceedings, public meetings, or notice.
- b. No experts were consulted.
- c. This VBAC Memo, once again, was developed in reaction to and retaliation for a birth center that had hired a physician to deliver VBAC clients.

Not only did the Department staff and officials neglect to consult professionals or experts with expertise in out-of-hospital birth, they also neglected to solicit advice from ANY department consultant or council, or even from legal counsel. According to the information produced in response to the Freedom of Information document, the “Memo” appeared to be the work of only one DHEC employee who printed a few blogs or reports from the Internet regarding VBAC, and then persuaded the Health Licensing Director to sign the Memo. One source cited in the response as a reference upon which the decision was allegedly based was, in fact, not obtained until AFTER the Memo was released.

ADMINISTRATIVE PROCEDURES ACT (APA)

It has also come to the attention of SC NACPM members that DHEC is making a practice of holding private meetings not open to the public, without prior public notice, in violation of the state Sunshine laws and the APA. We are specifically aware of two such incidences of these meetings: one meeting was with physician and hospital representatives (who are deemed "stakeholders" by the Department) regarding proposed LM and birth center regulations. The other meeting followed a scheduled Midwifery Advisory Council meeting, at which time neither the Emergency Measures issue, which was hotly debated, nor the Misoprostol Position Statement could be resolved. At that time, Ms. Thompson ended discussion regarding these topics by promising those in attendance that the Department would hold a private meeting “very soon” to resolve the issue. Ms. Thompson has since been contacted at least six times with request for the results of the meeting, but has not responded.

It is a violation of the due process and the state Administrative Procedure Act for an agency to alter a state regulation or significantly change the long-standing interpretation of an existing regulation without a notice and formal open commentary period. It is likewise a violation of due process and the state



APA for a state agency to take action in secret and off-the-record in promulgating, interpreting, and enforcing regulations. It is excessively unconscionable in a state that should be ruled by law for Licensed Midwives to be regulated in secret, by ad hoc rules, exceptions to rules, and obscure and unsupported interpretations.

South Carolina must have government in the sunshine and its administration agencies must act with transparency. Given the gravity of these concerns, SC NACPM calls upon the Department to issue a formal statement clarifying exactly how it interprets the Emergency Measures and consultation requirements, what exceptions will be recognized, and whether Ms. Thompson's statements with respect to that interpretation are accurate. We further call upon DHEC to reopen the Misoprostol statement and the VBAC statement for public review and discussion, and submitted in the form of proposed rules under the rulemaking requirements of the Administrative Procedure Act. As part of appropriate APA in SC, we likewise call upon DHEC to consult with experts in out-of-hospital maternity care, including such organizations as NACPM, NARM, the Birth Rights Bar Association, the American Association of Birth Centers, National Association of Birth Centers of Color, and Improving Birth. Finally, we call upon the Department to cease immediately its practice of holding private meetings with the direct competitors of Licensed Midwives and Birth Centers - that is, obstetricians and other physicians and hospitals

As this matter is of extreme importance, we are prepared to professionally collaborate on resolution of these issues. We respectfully request a response from the Department on or before July 21, 2015.

Respectfully
submitted,

South Carolina Chapter National Association of Certified Professional Midwives

Nicole Lavalley, President

Please respond to: Nicole Lavalley; nicole@birtheasy.com

CC:**Director Catherine E. Heigel**

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Attachments: LM Regulations Emergency Measures, DHEC VBAC Memo, DHEC Position Statement on Misoprostol for use by LMs, National Standards for Practice of CPMs, NARM CPM Issue Brief, DHEC reg 61-24 for Licensed Midwives, DHEC reg. 61-102 for Birthing Centers