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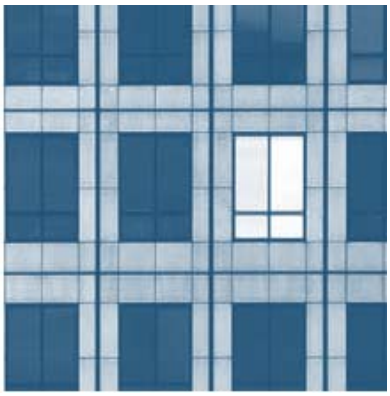
On the Subject



Health Industry Advisory

September 21, 2010

Proposed regulations for a new type of licensed health care facility in Illinois, the freestanding birth center, include significant requirements the centers will need to meet in order to operate, with comments on the proposed regulations accepted until October 4, 2010.

Illinois Issues Proposed Regulations for Freestanding Birth Centers

Three years after amendments to the Alternative Health Care Delivery Act, 210 Ill. Comp. Stat. 3/30 et seq., expanded Illinois public health demonstration programs to include freestanding birth centers (FBCs), regulations governing operation of FBCs have been proposed. The final regulations will be codified at 77 Ill. Admin. Code 265.

FBCs are permitted by law in more than 30 states in the United States. Practice in FBCs is focused on midwifery, minimal intervention, patient-directed maternity care models and the idea that pregnancy and childbirth are part of "wellness," rather than acute care. FBCs represent an alternative model of care that professes to provide quality outcomes on par with or exceeding that of hospitals for full-term deliveries; FBCs report cesarean section rates at half that of acute care hospitals. Licensing and regulatory requirements for FBCs vary widely by state.

By definition, FBCs in Illinois are facilities or locations "away from the mother's usual residence and in which births are planned to occur following a normal, uncomplicated, and low-risk pregnancy," with the centers "exclusively dedicated to serving the childbirth-related needs of women and their newborns … ." To the likely disappointment of alternative birth choice advocates, the act and the proposed regulations set forth a complex—and potentially costly—regulatory framework within which FBCs would need to operate to receive and maintain a license in Illinois. In contrast, hospital birth proponents may perceive the proposed regulations as more permissive than beneficial for maternity patients.

The proposed regulations are open for comment until October 4, 2010.

The Act

As provided by the act, FBCs are permitted only on a limited basis as part of a state-approved "demonstration project," with the following notable characteristics:

- Limit of 10 FBCs in the state with no more than 10 beds per FBC
- Licenses granted upon meeting all licensure criteria and a receipt of a Certificate of Need from the Illinois Health Facilities Services Review Board
- Total permissible number of FBCs in Cook, DuPage, Kane, Lake, McHenry and Will Counties is four (one of which must be owned or operated by a hospital and one of which must be owned or operated by a Federally Qualified Health Center (FQHC)
- Total permissible number of FBCs in other municipalities with populations less than 50,000 is three (one of which must be owned or operated by a hospital and one of which must be owned or operated by an FQHC)
- Total permissible number of FBCs in rural areas is three (one of which must be owned or operated by a hospital and one of which must be owned or operated by an FQHC)
- The first three FBCs developed under the act are to be located in or are to serve the primary care needs of residents of a health professional shortage area (HPSA); only five counties have no HPSA designation
- No more than two FBCs may operate in a single health-planning area for obstetric services, as such areas as defined by the Illinois Health Facilities Planning Act
- FBCs located outside of HPSAs are to be limited to locations that have a demonstrated need for obstetrical service beds (as determined by the Illinois Health Facilities Services Review Board) or there must be

a reduction in the existing obstetrical service beds in the planning area to prevent an increase in the total number of obstetrical service beds in the health planning area

- FBCs not operated under a hospital license must have a contractual relationship with an acute care hospital located nearby such that there is no longer than a 30-minute "decision to incision" time for cesarean section deliveries. Similarly, FBCs operated under a hospital license must be located proximate to that hospital such that there is no longer than a 30-minute "decision to incision" time for cesarean section deliveries.

- The medical director of an FBC must be a licensed, board-eligible or board-certified physician (or one with hospital obstetrical privileges) who is on-site or located within a close proximity of the FBC at all times.

Bottom Line

FBCs can be established only by specific owners/operators who comply with the requirements of the act and final regulations, when promulgated. Certain requirements are more stringent, and patients who desire a "low-tech, high-touch" delivery experience without physician involvement and outside of an affiliation with an acute care hospital, may not be satisfied the act provides the desired diversity in birth options for women in Illinois. In contrast, hospitals and FQHCs have a significant level of involvement as part of the demonstration project.

The Proposed Regulations

Building on the foundation provided by the act, the proposed regulations address general requirements and construction standards for FBCs in Illinois. Taken together, the 80 pages of proposed regulations would require FBCs to have many elements similar to hospital labor and delivery (L&D) units.

The regulations are "proposed" and subject to comment. They will be reviewed and potentially modified prior to final publication and implementation.

General requirements of note in the proposed regulations include the following:

- In addition to licensure, FBCs must be accredited by either The Joint Commission or the Commission for the Accreditation of Freestanding Birth Centers within two years of licensure.

- FBCs must have appropriate accreditation for lab testing and must make arrangements for testing beyond its capabilities at another lab services provider. Pharmacy services must be contracted out or managed on-site by a registered pharmacist.

- Procedures performed at FBCs are limited to those related to "uncomplicated childbirth" including simple episiotomies and repair of lacerations. No general anesthesia may be administered in FBCs. Newborn circumcisions may be performed at FBCs.

- Minimum length of stay after birth in an FBC is four hours; maximum length of stay in an FBC is 48 hours (or such other time limit as required by state law).

- An obstetrician, family practitioner or certified nurse midwife (referred to as a birth attendant) must be present around the clock from the time of patient admission through birth and throughout the immediate post-partum period, and a second staff person who is licensed or certified in Illinois in a health care-related field and is under the supervision of the physician or midwife and has specialized training must also be present at each birth (as the birth assistant). While not prohibiting the involvement of unlicensed individuals, such as doulas, in FBC births, the requirement for the presence of the birth attendant and birth assistant mean that at least two trained clinicians will be present for every birth in the FBC.

- FBCs must establish criteria for acceptance to the FBC and for transfer to a hospital for all patients. The collaborative agreement(s) in place between certified nurse midwives and physicians at the FBC shall be described in the FBC's protocols.

- The physician medical director or a physician designee meeting the medical director criteria described in the act must be available on-site at the FBC or located within a close proximity at all times. To be within "close proximity" means the ability to be physically present at the FBC within 30 minutes after being called. The FBC medical director must have full obstetrical privileges at a licensed hospital near the FBC.

- The medical director of the FBC makes the final determination on whether a patient is appropriate to receive care at the FBC.

- FBCs may not provide services to "walk-in" patients. Induction of labor is prohibited. Patients need a waiver from the FBC medical director to deliver at the FBC if the patient does not receive prenatal care at the FBC and does not register until or after 32 weeks' gestation.

- In addition to a letter of agreement/transfer agreement with a hospital that permits the FBC to meet the 30-minute "decision to incision" requirement, FBCs must also enter into a letter of agreement with a hospital designated under the state's Perinatal System to track data and report trends.
- FBCs must have a written agreement with an emergency medical transport provider or emergency medical services provider for emergency transportation of the mother and/or newborn infant to a hospital.
- Policies of the FBC must state that obstetric, pediatric and midwifery services are available at the FBC 24 hours per day, seven days per week, including obstetric and pediatric consultative services, transportation in case of emergency, and admission and discharge policies and procedures for referral to outside resources.
- The reporting requirements in the proposed regulations are also somewhat inconsistent in their current form, requiring the reporting of incidents that "had a significant effect on the health, safety or welfare of a client or clients" while specifying that incidents and accidents resulting in "no harm" to patients need not be reported.

Physical plant and construction standards in the proposed regulations are also noteworthy:

- Construction standards for FBCs incorporate by reference the American Institute of Architects standards for design and construction of health care facilities, as well as National Fire Protection Association Standards, Life Safety Code and other building code standards typical for health care facilities. The requirements of these codes will affect the ability for FBCs to be placed in non-traditional occupancies that have the true "homelike" qualities desired in such centers. Further, the cost of compliance with these codes may be prohibitive for FBC owners and operators who are not funded as part of a larger hospital/health care system or governmental clinic structure.
- Certain physical plan requirements, such as the requirements for call systems, emergency call systems and other systems, are consistent with those required in acute care hospitals. Note: The expense of such systems may be more than FBCs can afford, and stand to have an impact on the "high-touch, low-tech" approach generally desired by patients of FBCs.

Bottom Line

The proposed regulations include significant requirements FBCs may need to meet in order to operate in Illinois. The content of the final regulations is not yet known and may differ from the proposed regulations—particularly if there is a significant amount of comments received by the Illinois Department of Public Health during the comment period. Viewed by birth choice proponents as more restrictive and physician/hospital-friendly than in other states, the proposed regulations, if implemented, may be perceived positively by some constituencies as enhancing patient safety, and negatively by others as effectively requiring each FBC to function as a "mini-L&D unit" rather than to support an alternative birth experience.

Next Steps

View the proposed regulations in their entirety at http://www.mwe.com/info/pubs/register_volume34_issue34.pdf. Stakeholders have until October 4, 2010 (45 days after the August 20 publication date) to comment on the proposed regulations. Comments may be sent to Susan Meister, Division of Legal Services, Illinois Department of Public Health, 535 W. Jefferson, 5th Floor, Springfield, IL 62761 or via e-mail at mailto:dph.rules@illinois.gov.

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