Cabinet for Health and Family Services
Office of Certificate of Need
275 East Main Street – 4WE
Frankfort, Kentucky 40621

REQUEST FOR SHOW CAUSE HEARING

Re: Unauthorized Termination of Health Services at St. Luke Hospitals and Violation of Terms and Conditions of CON #019-07-5101(1)

As set forth below, Petitioners Candice Rich, who resides in Northern Kentucky and American Civil Liberties Union of Kentucky on behalf of its members living in, and/or using health services in, Northern Kentucky (ACLU KY) request, pursuant to 900 KAR 6:050E, Sections 18(1) and 18(5) (2009), that the Cabinet for Health and Family Services (the "Cabinet") conduct a show cause hearing to address and remedy the unauthorized termination of reproductive health services at St. Luke Hospitals. This Request by Petitioners Rich and ACLU of KY is supported by 15 individual residents of Northern Kentucky.[1]

INTRODUCTION

Prior to October 2008, St. Luke Hospitals (St. Luke) was the only hospital providing a comprehensive range of reproductive health services in Northern Kentucky. In 2008, in advance of an anticipated merger with a Catholic-affiliated hospital, St. Luke began planning to make substantial changes in the delivery of its reproductive health services. By October 2008, the merger was completed and St. Luke had terminated its practice of providing essential reproductive health services to the residents of Northern Kentucky. As a result, people residing within Northern Kentucky can no longer obtain birth control counseling, IUD insertion, infertility procedures, or tubal ligations at any hospital within the local community.

[1] Appendix 1 contains the names and counties of residence for each of these individuals.

In particular, there is now no place in Northern Kentucky where women can obtain tubal ligations at the same time they are already in the hospital for childbirth. This loss of services has substantially burdened Kentucky residents, particularly poor and low-income families relying on Medicaid who traditionally depended upon St. Luke for these services. Moreover, St. Luke made this substantial, and detrimental, change in health services in a manner that impermissibly bypassed Kentucky's certificate of need (CON) statute, which is intended "to improve the quality [of], and increase access to health-care facilities, services, and providers" for citizens of the Commonwealth. *See* KRS § 216B.010. In such circumstances, the Cabinet is fully authorized, and indeed obligated, to enforce the CON laws and regulations in order to take corrective action to protect the health care needs of Kentuckians.

Prior to discontinuing its reproductive health and family planning services, St. Luke, through its wholly owned subsidiary, Women's Health ASC, Inc, filed a CON application to build an ambulatory surgical center (ASC) that would provide reproductive health services. At the Cabinet's request, that application was supplemented in April 2008. Although the application, including the supplements, explained that certain family planning services currently available at the hospital would be moved to the new ASC because of the pending merger, it did not request authorization to terminate those services altogether. Nor did it address the extent to which relocating family planning services to an ASC might reduce the quality or quantity of services provided. Rather, it emphasized the critical importance of maintaining the full range of reproductive health services currently provided, and suggested that the restructuring would not cause a loss or reduction of such services in Northern Kentucky.

Based on those filings alone, and without a hearing, the CON application was granted in August 2008. Accordingly, there was no opportunity for the public, or the Cabinet, to

assess the true impact of the planned changes at St. Luke. Moreover, after receiving CON authorization to build an ASC, St. Luke and its Women's Health ASC failed to take any identifiable steps toward developing the facility and, as last reported to the Cabinet, apparently have no current plans to do so. As evidenced by its required progress reports to the Cabinet, despite the fact that St. Luke terminated its reproductive health services almost a year ago, there has been no progress on building the ASC, no promise as to when building will begin, and funding for it remains, at best, "under consideration."

As detailed more fully below, these actions by St. Luke violate the Kentucky CON statutory and regulatory requirements in at least two different ways. First, a substantial change in health services — which includes termination or reduction of health services — requires authorization from the Cabinet. Here, St. Luke neither applied for, nor received, a CON authorizing it to terminate or reduce its delivery of reproductive health services. And, because the CON application to build an ASC failed to give a clear and complete explanation of the diminishment in services that would result from relocating those services to the ASC, it is insufficient to constitute an application to make a substantial change in health services at St. Luke Hospitals. Second, even if the CON were construed as authorization for St. Luke to restructure (not terminate or reduce) reproductive health services by building an ASC, St. Luke, through its subsidiary, has wholly failed to comply with the goals, timetables, and progress report requirements of that CON. This failure to comply with the terms and conditions of the CON also constitutes a violation of the statutory and regulatory requirements for operating health facilities.

Either of these violations represents an independent and adequate basis upon which the Cabinet may rely in ordering a show cause hearing pursuant to 900 KAR 6:050E, Section 18. Given the urgency of the situation and the importance of these services to Northern

Kentuckians, investigation and intervention by the Cabinet is warranted. As was stated by St. Luke Hospitals/ Women's Health ASC in its application to build the ASC, it is "imperative" to preserve "complete" and "local" access to reproductive services in Northern Kentucky, particularly for residents who are "indigent or on Medicaid." *See infra* at 5. Unfortunately, almost a year ago, St. Luke Hospitals stopped providing these "imperative" services and, as indicated by all available records, will not resume without the Cabinet's intervention.

I. ACCESS TO FULLY INTEGRATED REPRODUCTIVE HEALTH SERVICES IS CRITICAL TO THE HEALTH AND WELL-BEING OF WOMEN AND FAMILIES IN NORTHERN KENTUCKY.

A. Family planning services improve the health and lives of women and families.

Family planning services, including access to postpartum birth control counseling and services and tubal ligations, are part of the continuum of reproductive health services critical to the well being of women and their families. Indeed, improving pregnancy planning and spacing, and preventing unintended pregnancies — because this in turn improves both maternal and infant health — is one of the top goals of Healthy People 2010, which set forth the nation's public health goals. *See* U.S. Department of Health and Human Services, *Healthy People 2010: Understanding and Improving Health, Objectives for Improving Health*: Objective 9: Family Planning (Nov. 2000), *available at* http://www.healthypeople.gov/document/pdf/Volume1/09Family.pdf.[2] Consistent with this

[2] Specifically, the following harms are among those attributed to a lack of family planning services:

> Unintended pregnancy in the United States is serious and costly and occurs frequently. Socially, the costs can be measured in unintended births, reduced educational attainment and employment opportunity, greater welfare dependency, and increased potential for child abuse and neglect. Economically, health care costs are increased. An unintended pregnancy, once it occurs, is expensive no matter what the outcome. Medically, unintended pregnancies are serious in terms of the lost opportunity to prepare for an optimal pregnancy, the increased likelihood of infant and maternal illness, and the likelihood of abortion. The consequences of unintended pregnancy are not confined to

nationwide approach to women's health, and reflecting the critical importance of maintaining such services in Northern Kentucky, St. Luke itself explained to the Cabinet:

> Kentucky is currently rated 50th in the country for women's health and wellness issues. Reproductive health is a basic women's health service to which any female resident of Northern Kentucky should have access. Also complicating that issue is that 50% of Kentucky low income mothers who work out of the home do not have health insurance. This endeavor [to build an ASC] will preserve reproductive access to health care in Northern Kentucky which is so important for just these reasons.

CON #019-07-5101(1), at 9 (Mar. 26, 2008) (hereinafter "CON App.") (Ex. A). Moreover, St. Luke further stated, "it is imperative that local access be preserved for those that are indigent or on Medicaid. These services would not be available outside the state to those individuals." *Id.* at 6.

The ongoing loss of comprehensive family planning services in Northern Kentucky will have a devastating effect on women and their families. More than 98% of American women of reproductive age use contraceptives at some point in their lives. Mosher WD, et al., *Use of Contraception and Use of Family Planning Services in the United States*: 1982-2002, Advance Data from Vital Health Statistics, No. 350, National Center for Health Statistics (2004), *available at* http://www.cdc.gov/nchs/data/ad/ad350/pdf. As discussed above, they do so to the benefit of their own lives and those of their children. In fact, the Centers for Disease Control and Prevention declared family planning one of the ten most significant public health achievements of the 20th century. *Ten Great Public Health Achievements – United States, 1900 -1999*, 48 Morbidity & Morality Wkly. Rep. 241, 242 (1999), *available at* http://www.cdc.gov/mmwr/PDF/wk/mm4812.pdf.

> those occurring in teenagers or unmarried couples. In fact, unintended pregnancy can carry serious consequences at all ages and life stages.

Id. at 9-5; *see also id.* at 9-14 (discussing health benefits of spacing births).

Moreover, as explained by Dr. Franklin, an obstetrician-gynecologist who regularly cares for low-income and uninsured women in Kentucky, family planning services "significantly impact women's lives." *See* Declaration of Tanya E. Franklin, M.D., M.S.P.H. ¶11 (hereinafter "Franklin Decl.") (Ex. O). Dr. Franklin also observes that in order for her low-income patients to have effective access to family planning services, it is important that these services remain available in a hospital setting. *Id*. This is particularly true with respect to postpartum tubal ligations, one of the services St. Luke previously provided. *See* Declaration of Candice Rich at ¶¶4-5, 8 (hereinafter "Rich Decl.") (Ex. N).

B. Hospital-based family planning services can offer advantages medically, financially, and in terms of overall accessibility.

Sterilization, which has "near-perfect effectiveness," is the most common method of contraception in the United States. *Healthy People 2010*: Family Planning at 9-4. Tubal ligation, the method of sterilization for women, often involves a surgical procedure that requires an abdominal incision. Franklin Decl. ¶¶ 3-7 (Ex. O). While the procedure is generally quite safe, it carries the same risks as any surgery, including bleeding, infection and the general risks for anesthesia — allergic reactions to medicines, breathing problems or pneumonia, and heart problems. *See* U.S. National Library of Medicine and National Institutes of Health, *Medline Plus Encyclopedia* (updated Feb. 9, 2009), *available at* http://www.nlm.nih.gov/medlineplus/ency/article/002913.htm. For a pregnant woman who plans on having a tubal ligation, "there are significant benefits in terms of reduced medical risks, improved access, and reduced costs when the procedure is performed immediately after childbirth, while she is still in the hospital." Franklin Decl. ¶3 (Ex. O).

A surgical tubal ligation performed immediately after childbirth (a "postpartum tubal") is procedurally simpler, and thus less risky, than one that is not performed after recent

childbirth (an "interval tubal"). In the case of a woman who has just delivered by cesarean section, there is no need for an additional round of anesthesia or a second surgery. The procedure is simply performed at the same time as the cesarean. *Id.* ¶4. If a woman delivers vaginally, while a surgery will be required, because her uterus is still enlarged it facilitates easier access to the fallopian tubes and enables a simpler surgical procedure than is used to perform an interval surgical tubal ligation. *Id.* ¶¶5-6. This means less risk of potential injuries such as damage to internal organs, including the intestine, uterus, ovaries and large blood vessels in the abdomen and pelvis. *Id.* ¶7. In addition, only a spinal block is required, which is less risky than the general anesthesia used for interval tubal surgery. *Id.* ¶¶6, 9. A postpartum tubal does not extend the hospital stay for women, regardless of whether they gave birth vaginally or by cesarean. *Id.* ¶¶4-5.

Also, postpartum tubal ligations prior to hospital discharge are fare more accessible and affordable for many women because returning for a later procedure will require more money and more time away from work or childcare obligations, including caring for a newborn. In particular, for low-income or uninsured women who qualify for Medicaid related only to pregnancy, if a tubal ligation is not available as part of their postpartum care, they face the prospect of costs well over $1,000. *See* Supplement to CON App., Substitute p. 20 (Apr. 25, 2008) (hereinafter "CON App. Supp.") (Ex. B) (listing tubal costs of $1300 to $2000); *see also* Franklin Decl. ¶9 (Ex. O) (explaining Medicaid coverage during pregnancy and $1100 cost for interval tubal not including cost of anesthesia).

Thus, by having access to the procedure immediately postpartum, a woman can avoid increased medical risks, a second recovery period, and the significantly higher costs of a later surgical procedure. Indeed, for some low-income women, the higher cost of a separate procedure would be prohibitive. *See* Franklin Decl. ¶10 (Ex. O). It was for all of these

reasons that Petitioner Rich, who was relying on a combination of employer insurance and Medicaid to cover her pregnancy expenses, planned on a postpartum tubal ligation at St. Luke. *See* Rich Decl. ¶5-6 (Ex. N). Unfortunately, as detailed in her declaration, despite going to St. Luke for all her obstetrical needs throughout her pregnancy, and repeatedly making clear her desire for a postpartum tubal ligation, she was told — two days after her estimated due-date — that a cesarean section was recommended, but that tubal ligations were no longer available at St. Luke Hospitals. *See* Rich Decl. ¶¶ 2, 7-8 (Ex. N). Facing this unexpected news, she was forced to make a choice between foregoing the postpartum tubal ligation or scrambling to switch obstetricians and hospitals at the eleventh hour. In the end, she went to an out-of-state hospital for both her delivery and tubal ligation at great financial and emotional expense to her and her family. *Id.* ¶¶9-13. Such an abrupt, and unplanned, switch in providers also undermines what the Institute of Medicine identifies as a critical principle in improving the quality of health care for patients – a continuous relationship between patients and clinicians. *See* Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century*, (2001), at 1, 3, *available a*t http://www.iom.edu/Object.File/Master/27/184/Chasm-8pager.pdf.

Unfortunately, despite the clear imperative to ensure accessible and effective family planning services as part of women's basic health care in Northern Kentucky, St. Luke failed to explain to the Cabinet the implications of removing all tubal ligations from the hospital setting, and, in fact, is no longer providing this procedure or other basic reproductive health services in any setting. *See infra* at 13, 16-17. In light of the immense benefits of family planning services to women and children's health, and the struggle of women, particularly low-income women, to access those services in Northern Kentucky, the substantial change in

health services at St. Luke Hospitals must be thoroughly investigated and appropriately remedied.

II. STATUTORY AUTHORITY

The Kentucky legislature enacted Chapter 216B of the Kentucky Revised Statutes (KRS) with the intent to:

> [I]nsure that the citizens of this Commonwealth will have safe, adequate, and efficient medical care . . . . Therefore, it is the purpose of this Chapter to fully authorize and empower the Cabinet for Health and Family Services to perform a certificate-of-need function and other statutory functions necessary to improve the quality and increase access to health-care facilities, services, and providers, and to create a cost-efficient health-care delivery system for the Citizens of the Commonwealth.

KRS § 216B.010 ("Legislative findings and purposes"). The Chapter's CON provisions are one of the principle mechanisms by which the Cabinet is empowered to oversee and enforce those statutory purposes and requirements. *See* KRS § 216B.061 (regarding circumstances requiring CON); KRS § 216B.086 (regarding revocation of CON). Moreover, the Chapter also requires the Cabinet to promulgate administrative regulations that fully implement and enforce those statutory provisions. *See* KRS §§ 216B.040; 216B.062; and 216B.075.

Thus, the statutory CON provisions together with the Cabinet's administrative regulations, *see* 900 KAR 6:050E, create a binding legal framework that apply to the actions of St. Luke Hospitals, its subsidiaries, and any other health facility responsible for the termination of reproductive health services previously available at St. Luke. More specifically, and as outlined in detail below, three critical aspects of the CON statutes and regulations authorize the relief sought by this petition; those that: 1) prohibit certain changes in health services unless they are first authorized by the issuance of a CON; 2) require health entities to comply with the conditions of a CON once issued; and 3) enable, and in some circumstances require, the Cabinet to enforce various provisions of the CON laws.

First, the CON law mandates that no person[3] or health facility shall "make a substantial change in a health service" "without first obtaining a certificate of need." KRS § 216B.061(1)(d); *see also* KRS § 216B.015(8) (defining certificate of need as "an authorization by the cabinet to . . . substantially change a health service"). By definition, a "reduction or termination of a health service which had previously been provided in the health facility," constitutes a substantial change in a health service. *See* KRS § 216B.015(28)(c) (defining "substantial change in a health service").

Second, once issued, a holder of a certificate of need is statutorily bound "to implement the project in accordance with timetables and standards for implementation established by administrative regulation of the cabinet." KRS § 216B.086 (establishing that failure to comply with such regulations is basis for revocation); *see also* 900 KAR 6:050E, Section 20 ("Timetables and Standards for Implementation"). Pursuant to these administrative regulations, submission of six month progress reports constitutes a "condition for the issuance of a certificate of need" until a project is fully implemented. *Id.* at Section 20(1). The six month progress reports must demonstrate that the required elements for progress have been completed, or, if not, that "(a) The failure was due to emergency circumstances or other causes that could not reasonably be anticipated and avoided by the holder; or (b) Were not the result of the action or inaction of the holder." *Id.* at Sections 20(3), (6); *see also id.* at Sections 20(9) to (15) (setting forth required elements of six month progress reports). Unless the Cabinet determines that such exigent circumstances have been shown, the Cabinet "shall notify the holder of the certificate of need, in writing, that it has determined to revoke the certificate of need," and that decision will become final thirty days after such notice unless the holder requests a hearing. *Id.* at Sections 20(7), (8).

[3] A "person" is defined to include partnerships and corporations. *See* KRS § 216B.015(21).

Finally, the CON statute broadly empowers the Cabinet to "enforce, through legal actions on its own motion, the provisions of this chapter and its order and decisions issued pursuant to its functions." KRS § 216B.040(1)(d). As part of this enforcement authority, the Cabinet may "[a]dminister oaths, issue subpoenas, subpoenas duces tecum, and all necessary process in proceedings brought before or initiated by the cabinet, and the process shall extend to all parts of the Commonwealth." KRS § 216B.040(3)(b).

One of the principle mechanisms for oversight and enforcement is a "Show cause hearing," in "which it is determined whether a person or entity has violated provisions of KRS Chapter 216B." 900 KAR 6:050E, Section 1(22) (defining "Show cause hearing"); *id.* at Section 18 (setting forth bases for show cause hearing). The cabinet "*shall . . . conduct* a show cause hearing regarding terms and conditions which are a part of a certificate of need approval and license at the request of any person." *Id.* at Section 18(5) (emphasis added). At that hearing, the Cabinet "shall determine" whether the health facility or service is "in violation of any terms or conditions which are a part of that certificate of need." *Id.* at 18(6); *see also id.* at Section 18(18) (setting forth enforcement process). Additionally, the Cabinet may also conduct a show cause hearing "on its own initiative or at the request of an affected person. . . to determine if a person has established or is operating a health facility or health service in violation of ... KRS Chapter 216B or this administrative regulation ...." *Id.* at Section 18(1). Such requests "shall be accompanied and corroborated by credible, relevant, and substantive evidence, including an affidavit or other document which demonstrates that there is probable cause to believe" that a health service or entity is operating in violation of Chapter 216B or the administrative regulations. *Id.* at Section 19(2). "If a violation is found to have occurred as a result of a show cause hearing ... the cabinet *shall* take action as provided by KRS Chapter 216B." *Id.* at Section 18 (17)(emphasis added).

III. A Show Cause Hearing Should Be Held Because St. Luke Hospitals Terminated Reproductive Health Services Without Properly Requesting, or Receiving, Prior Cabinet Authorization.

Prior to October 2008, St. Luke Hospitals, through its birthing center, Center for Reproductive Health, Adolescent OB/GYN Center, as well as OB/GYN offices in Ft. Thomas, Florence, Falmouth and Crittenden, provided Northern Kentucky's most comprehensive reproductive health services to Grant, Pendleton, Gallatin, Owen, Carroll, Boone, Kenton and Campbell counties, including family planning counseling and services, IUD insertions, tubal ligations, and fertility counseling and procedures. *See* CON App. at 3, 6 (Ex. A); *see also* Coalition Letter to Cabinet (November 21, 2008) (Ex. C) (documenting concern about apparent loss of these reproductive health services to these counties). In order to clear the way for a merger with St. Elizabeth Medical Center, St. Luke eliminated these reproductive health services by October 2008 because they are not permitted under the *Ethical and Religious Directives for Catholic Health Care Services* which are applicable to St. Elizabeth and its affiliated entities. *See* CON App. at 5-6 (Ex. A); Coalition Letter to Cabinet (Ex. C); *see also Press Release: St. Elizabeth and St. Luke Merger Completed* – 10/27/2008, *available at* http://www.stelizabeth.com/about/news/index.asp?straction=readarticle&article=article_20081028_110542_live.

Public records requests filed prior to (and after) the merger between St. Luke and St. Elizabeth Medical Center demonstrate that there were no filings that clearly and expressly sought authorization to completely terminate these, or other, reproductive health services at St. Luke. Rather, the only authorization St. Luke sought with respect to the delivery of reproductive health services was an application to build a reproductive health ambulatory surgical center to be operated by its wholly owned subsidiary, "Women's Health ASC, Inc."

CON App. at 1, 6 (Ex. A). However, as discussed below, that application in no way suffices as one to wholly "terminate," or even "reduce," the specified health services, and the CON issued clearly does not authorize such a drastic result. Moreover, as is discussed in Part IV, there has been *no* progress on building the ASC; thus, St. Luke has not complied with the terms of the CON granted.

On March 26, 2008, "Women's Health ASC, Inc.," which was "established as a wholly owned subsidiary of St. Luke Hospitals, Inc." submitted a CON application to build an ASC that would provide "key" reproductive services and procedures. *See* CON App. at 2-3 (Ex. A). The application explained the need for this new ASC as follows:

> Reproductive needs that include birth control counseling, sexual counseling, IUD insertion, fertility counseling and services, reproductive/fertility procedures, and tubal ligations cannot be performed at any Catholic affiliated hospital under Catholic Directive #69. With the proposed merger of the two Northern Kentucky hospitals under the direction of the Catholic Directives, these services will not be able to be provided in or by the hospitals. ... Therefore, without the addition of a stand alone ASC for reproductive services, the Northern Kentucky areas will be without a facility to support women's reproductive health care needs.

Id. at 5-6. Further elaborating on this issue, the application states "it is imperative that local access be preserved for those that are indigent or on Medicaid. These services would not be available outside the state to those individuals." *Id.* at 6. Indeed, the application goes on to emphasize the critical role of reproductive services as a component of improving women's health in Kentucky, citing it as a "basic women's health service to which any female resident of Northern Kentucky should have access," including the large percent of uninsured low-income mothers in the region. *Id*. at 9.

The application promises that, as a subsidiary of St. Luke, the Women's Health ASC has all the financial resources necessary to provide these services and that "surgery and procedural events will be performed by the same physicians that are currently practicing at

both St. Elizabeth and St. Luke." *Id.* at 6. Also, because it is "a subsidiary of St. Luke Hospitals, Inc. the entity will provide sufficient management and clinical expertise to meet the program goals." *Id.*; *see also id.* at 13-14 (indicating all funds to be generated internally). Finally, the application projected December 2008, as the date for "Completion and Operation of Project." *Id*. at 22.

By letter dated April 10, 2008, the Cabinet directed St. Luke to submit specific additional information necessary to complete the application. J. Cracraft Letter to N. Barone Kremer at St. Luke Hospitals (Apr. 10, 2008) (Ex. D). Notably, this included a request for "documentation from the two hospitals that reorganization and merger will be taking place and [to] provide a time frame," projections of the services that the ASC would provide in 2009 and 2010, and documentation that "internal funds are available to fund the project." *Id*. at 2. In response, on April 25, 2008, Women's Health ASC submitted an explanatory letter and numerous substitute pages with responsive information. *See* Con App. Supp. (Ex. B). As supplemented by the April 25 correspondence, the application reiterated the same need to maintain "key" reproductive health services currently provided by St. Luke Hospitals. *Id*. at 3, 5-6. The supplemented CON application included details on the merger timeline, which was to be finalized no later than December 2008, confirmation and documentation that all necessary funds were available internally, and also proposed a new "completion and operation of project" date of March 2009, notably well past the anticipated merger deadline. *Id*. at 6, 14, 22, Appendix 6.

Without holding a hearing, the Cabinet approved the certificate of need application on August 13, 2008, *see* Final Order In Re: Women's Health ASC, Inc. (Aug. 13, 2008) (Ex. E),[4]

[4] The Final Order was corrected by Amended Final Order dated August 18, 2008 (Ex. F). The Amended Final Order simply corrected a mistake in identifying the address of the ASC and its county of location.

and issued the final Certificate of Need on September 22, 2008. *See* Certificate of Need # 08-080 (Sep. 22, 2008) (Ex. G). As approved, the certificate of need authorizes the establishment of an "ambulatory surgery center limited to reproductive services." *Id.* The certificate of need does not authorize that those services be wholly terminated within St. Luke, let alone in the absence of their sufficient replacement and relocation at the ASC.

Moreover, because St. Luke's application did not fully identify the scope and impact of the planned changes, the Cabinet did not have an adequate opportunity to weigh and consider whether it would be appropriate to authorize such a substantial change in services. To the contrary, in the application to establish a reproductive health ASC, St. Luke represented that it recognized the critical need to maintain reproductive health services for residents of Northern Kentucky and would make arrangements — through that ASC — to fully continue providing those services despite the then-pending merger with St. Elizabeth.[5] Based on this representation, the Cabinet did not have sufficient notice of the detrimental impact the merger would have on reproductive health services for northern Kentuckians. For example, the CON application fails to address how women who give birth at St. Luke and seek immediate postpartum tubal ligations will continue to receive those services. [6] Thus, if

[5] Based on publicly available reports and open records obtained from October 2008 through September 2009, upon information and belief, neither St. Luke, nor St. Elizabeth Medical Center submitted any further notices, or CON applications, pertaining to a change in services at St. Luke. The only other filing regarding the merger was an "Acquisition of a Health Facility Notice of Intent" filed by Saint Elizabeth Medical Center, after the ASC CON was approved. *See* St. Elizabeth Medical Center Notice of Intent to Acquire (Aug. 29, 2008) (Ex. H). That Notice of Intent made no mention of any plan to terminate health services at St. Luke or its subsidiaries upon the completion of the merger. Thus, not surprisingly, in acknowledging this notice of intent, the Cabinet did not inquire further into the potential loss of reproductive health services at St. Luke, or require a certificate of need for the merger, but only cautioned that "[a]fter this transaction, if the purchaser desires to change the health service(s) . . . or in fact, pursue any other organizational changes, a new notice or a certificate of need may be required." *See* Letter from Director C. Banahan to J. A. Dietz (Sep. 8, 2008) (Ex. I).

[6] Also, the CON application states that St. Luke Hospitals, as a contracted provider of reproductive health services including IUD placement and tubal ligations for patients screened at two Kentucky Health Department locations, would continue to "support its long term commitment with these Health Departments." CON App. at 8 (Ex. A). There are real questions as to whether the ASC could adequately fulfill the obligations to these state agencies and the clients they serve.

the Cabinet and the public were forthrightly advised through compliant filings and disclosures, hearings likely would have been requested and held to explore how moving reproductive health services outside the hospital setting will impact access, coverage, continuity of care, and efficiency of reproductive health care for families in Northern Kentucky. In turn, considerations of these factors might have led to much different conditions for authorizing the restructuring of reproductive health services at St. Luke.

Thus, because St. Luke never sought or obtained a certificate of need to wholly terminate particular reproductive health services, it is currently operating a health facility in violation of the Kentucky certificate of need statutes. *See supra* Part II. Further, the failure to timely, directly, and clearly acknowledge how moving these services to an ASC would change the quality and availability of reproductive health care to women in Northern Kentucky is particularly troubling in light of the representation to the Cabinet that services would continue without substantial change in quality or access. Accordingly, the Cabinet should hold a show cause hearing pursuant to Section 18(1). Moreover, pursuant to its statutory enforcement authority under KRS § 216b.040(1)(d), the Cabinet should also require St. Luke to immediately resume the delivery of all reproductive health services previously provided on the basis that the Cabinet did not receive an application to terminate or reduce such services and no such authorization was granted.

IV. A Show Cause Hearing Must Be Held Because St. Luke Hospitals, And its Subsidiaries, Violated The Terms and Conditions of the Certificate of Need Authorizing Construction of an ASC.

In addition to St. Luke Hospitals' failure to seek appropriate authorization to eliminate reproductive health services, it has also failed to abide by the terms and conditions of the certificate of need as issued which requires continuation of those services in an ambulatory surgical setting.

On March 25, 2009, the Cabinet sent a letter to Women's Health ASC stating that the required six month report had not been received and granting a one month extension for its submission. *See* Director C. Banahan Letter to J. Way (Mar. 25, 2009) (Ex. K). In April, a response letter was submitted to the Cabinet indicating that Women's Health ASC, Inc. had changed its location and its name to "Women's Health of Northern Kentucky." The requested six month progress report accompanied the letter under the new corporate name and address. *See* J.E. Lange III Letter to Director C. Banahan and attached Progress Report (April 16, 2009) (Ex. K) (hereinafter "Progress Report"). The Progress Report indicated that the ASC was not completed, that it was not in "conformance to original timetable," that a financial commitment was still "Under Consideration," and that problems had been encountered. The problems encountered were described incompletely and vaguely as follows:

> Due to the timing of the merger between the St. Luke Hospitals and the St. Elizabeth Medical Center, as well as the transition of the Community Foundation of Northern Kentucky, the potential of this project has been substantially delayed. The merger agreement provided for Women's Health ASC. Inc. to be assumed by the Community Foundation of Northern Kentucky, Inc., which now owns and controls Women's Health ASC, Inc. including the CON for its ASC. Hopefully, there will be greater detail on the next progress report.

Progress Report (Ex. K). No information, other than a reference to the above statement, was provided in response to the sections that required explanation of "extenuating circumstances," "ability to complete proposal," "expected date of completion," and "any changes contemplated." *Id.*

Apparently, just this month, another progress report was received by the Cabinet. *See* J.E. Lange III Letter to M. Heim and attached Progress Report (stamped received Sept. 1, 2009). It reiterates the same "problems encountered" as in the first progress report while adding, without elaboration, that "[p]reviously identified professional providers of service have not committed to staff center due to the merger," and that there is "generally a change in

how women's health services are being delivered in the Northern Kentucky area." *Id*. ¶5. As to "extenuating circumstances," the report only asserts vaguely that resources have been "negatively affected by the down turn in the financial markets." *Id.* ¶ 6

Neither of these six month reports satisfy statutory or administrative requirements. As discussed in Part II *supra*, the certificate holder carries a heavy burden to justify any failure to comply with the conditions of a certificate of need, including any deviations from approved timetables. Specifically, if the required elements for progress have not been completed at the time of the first six month progress report, the certificate holder must demonstrate that it was "due to emergency circumstances or other causes that could not reasonably be anticipated and avoided by the holder," or were not otherwise "the result of the action or inaction of the holder." *See* 900 KAR 6:050E, Sections 20(3), (6). These Progress Reports do not (and cannot) satisfy this requirement.

Since at least March 2005, St. Luke prepared for its merger with St. Elizabeth and anticipated a completed merger no later than December 2008. Thus, it is simply unacceptable to attribute the failure to make *any* progress on the ASC to the "timing of the merger" — something planned and known months in advance. Moreover, the failure of St. Luke Hospital/Women's Health ASC to take any steps in the past year toward building the ASC, cannot simply be justified with unsupported statements about the financial commitment changing from confirmed to "uncertain" to "negatively affected." Finally, a second progress report that for the first time mentions additional problems nearly a year after the CON was granted, and six months after the promised completion of the project, cannot fairly be claimed as identifying "emergency" circumstances that "could not reasonably be anticipated."

For these reasons, the Cabinet's April 30, 2009, letter confirming receipt of the first six month progress report and stating that the report "complies with the requirements set forth

in 900 KAR 6:050, Section 20," is particularly troubling and should be reconsidered. *See* Director C. Banahan Letter to J. Schwegman (April 30, 2009) (Ex. L). Likewise, the second progress report should not be approved. Unless, and until, St. Luke Hospitals, the Women's Health ASC, or the current CON holder, can fulfill their obligation to demonstrate concrete "emergency circumstances" or conditions that were not foreseeable and were beyond their control, they should be put on notice that they are in violation of the CON laws. Indeed, because compliance with proposed timetables, including the completion of a reproductive health services ASC by March 2009, and compliance with the progress report requirements are all part of the terms and conditions of the CON, and because this Petition sufficiently identifies noncompliance with those conditions, the Cabinet is required to conduct the requested show cause hearing regarding the alleged noncompliance. 900 KAR 6:050E, Section 18(5) (Cabinet "shall [] conduct a show cause hearing regarding terms and conditions which are a part" of that CON). Moreover, under its statutory enforcement authority, *see* KRS §§ 216b.040(1)(d), 216B.086, the Cabinet should modify the certificate of need that authorizes construction of the Women's Health ASC to explicitly require St. Luke to continue providing all pre-existing reproductive health services until completion of the ASC; set new timetables and standards for construction of the ASC; and require meaningful assurances, sufficient documentation, and additional progress reports to ensure that revised goals and timelines are met.

CONCLUSION

St. Luke effectively eliminated its longstanding delivery of family planning services to the residents of Northern Kentucky in a manner that undermined the letter and intent of the CON laws and that was contrary to its own promise to ensure continuation of those services. It is clear that this situation, which has persisted for nearly a year, will not be remedied without meaningful enforcement of the CON laws by the Commonwealth. For all of the foregoing reasons, we respectfully request the Cabinet conduct a show cause hearing pursuant to 900 KAR 6:050E, Sections 18(1) and 18(5).

Respectfully submitted,

Diana Kasdan, Staff Attorney
ACLU Foundation
Reproductive Freedom Project
125 Broad Street, 18th Floor
New York, NY 10004
(212) 549-2633
(212) 549-2652 (fax)
dkasdan@aclu.org

William E. Sharp, Staff Attorney
David A. Friedman, General Counsel
ACLU of Kentucky
315 Guthrie Street, Suite 300
Louisville, KY 40202
(502) 581-9746
(502) 589-9687 (fax)
sharp@aclu-ky.org
dfriedman@ffgklaw.com