

4/21/22

1 PM spoke with Erin Kin MD Executive Director, regarding the letter of 4/3/2023, requesting variances for some of the ASTC regulations. Explained that there are no waivers, and these are required elements per the Act and the Code. Informed them of the option not to be licensed as an ASTC as per the Code and the Act

(210 ILCS 5/3)

The term "ambulatory surgical treatment center" does not include any of the following:

6) Any facility in which the performance of abortion

procedures, including procedures to terminate a pregnancy or to manage pregnancy loss, is limited to those performed without general, epidural, or spinal anesthesia, and which is not otherwise required to be an ambulatory surgical treatment center. For purposes of this paragraph, "general, epidural, or spinal anesthesia" does not include local anesthesia or intravenous sedation. Nothing in this paragraph shall be construed to limit any such facility from voluntarily electing to apply for licensure as an ambulatory surgical treatment center.

Adm Code 205.110

The term "Ambulatory Surgical Treatment Center", for the purposes of this Part, does not include:

Other Facilities: *Any facility in which the performance of abortion procedures, including procedures to terminate a pregnancy or to manage pregnancy loss, is limited to those performed without general, epidural, or spinal anesthesia, and which is not otherwise required to be an ambulatory surgical treatment center. For purposes of this definition, "general, epidural, or spinal anesthesia" does not include local anesthesia or intravenous sedation. Nothing in the Act and this Part shall be construed to limit a facility of this type from voluntarily electing to apply for licensure as an ambulatory surgical treatment center. (Section 3(A) of the Act)*

Se is aware and will consider the agency's options.



Illinois Department of Public Health
Health Care Facilities and Programs
Division of Health Care Facilities and Programs
525-535 West Jefferson Street
Springfield, IL 62761-0001

April 3, 2023

Re: License: 7001084 – Request for Variance

Hope Clinic for Women Ltd is requesting a variance on the following three subsections of the regulations in Part 205 of the Illinois Administrative Code.

TITLE 77: PUBLIC HEALTH

CHAPTER I: DEPARTMENT OF PUBLIC HEALTH

SUBCHAPTER b: HOSPITAL AND AMBULATORY CARE FACILITIES

PART 205 AMBULATORY SURGICAL TREATMENT CENTER LICENSING REQUIREMENTS

REQUEST #1

Section 205.230 Standards of Professional Work

- a) 5) Each member of the medical staff granted specific surgical practice privileges shall provide, at every re-credentialing period, a notarized statement or documentation indicating the name of the Illinois licensed hospital or hospitals where he or she has skilled-equivalent practice privileges. The statements or documentation shall be available for Department inspection. A list of privileges granted to each medical staff member of the ambulatory surgical treatment center shall be available at all times for facility staff use and for Department inspection. As used in this subsection (a)(5), "skilled-equivalent" means the ability to perform similar procedures requiring the same level of training and expertise.

Current Hope Clinic policies require medical staff with surgical practice privileges to maintain active skilled-equivalent practice privileges at an Illinois hospital in compliance with this regulation.

Variance requested:

Revise Hope Clinic policy to require medical staff with surgical practice privileges to have documentation of skilled-equivalent training and experience. Examples of this documentation would include residency, fellowship, or post residency training, work experience, or skilled-equivalent practice privileges in an inpatient or outpatient setting.

This information would be collected and documented in the:

Standard Illinois Health Care Professional Credentialing (or recredentialing) and Business Data Gathering Form

Explanation: Current Hope Clinic surgical procedures (first and second trimester abortion, D&C, D&E) are almost exclusively outpatient procedures. A patient rarely would require inpatient treatment for these procedures. Many providers with excellent training and experience that would provide high quality medical care at Hope Clinic are excluded from working at our facility secondary to the active IL hospital privileges requirement. These providers either have hospital privileges in other states and/or their current work does not require hospital privileges at all.

Effects on medical care: There would only be positive effects on the already high quality patient care and the high standards to which the facility holds the medical staff. Patients that require inpatient care known pre-operatively are referred to a hospital based setting and providers that work in hospital based settings that can provide this care. In the area local to Hope Clinic there are no inpatient facilities that provide abortion care. Currently this is just available in the Chicago area. Patients that require inpatient care post-operatively are referred to known providers at a hospital local to Hope Clinic that specialize in *post-operative* medical issues that require hospital based care.

Benefits for Hope Clinic: The change would allow Hope Clinic to significantly increase the number of available qualified providers at the facility – which is critical to continued quality patient care. The patient volume at Hope Clinic continues to increase as restrictions on abortion across the country are enacted. Restrictions on providers by employers and hospitals continues to increase, as well, which limits the available providers in the local area.

Illinois is supportive of the efforts of medical providers in the state to increase capacity for abortion care. Public Act 102-1117 (January 2023) describes “Temporary permits for health care” which clearly is intended to address the current shortage of providers of abortion care in this state. (*Referenced below*)

REQUEST #2

Section 205.530 Operative Care

- a) Surgical procedures shall be performed only by a qualified physician, dentist or podiatrist within the limits of the defined specific surgical practice privileges that have been granted to that individual by the consulting committee or a committee designated by the consulting committee.

Current Hope Clinic policies require that all surgical procedures are performed by a physician in compliance with this regulation.

Variance Requested:

Revise Hope Clinic policy to include: “performed only a qualified physician, an advanced practice registered nurse or physician assistant that have been granted to that individual be the consulting committee”.

Explanation: Aspiration abortion in the outpatient setting can be safely completed by an advanced practice registered nurse or physician assistant with appropriate training and experience. This was recognized by the state of Illinois in Public Act 102-1117 (January 2023) (775 ILCS 55/1-25) A health care professional may provide abortion care in accordance with the health care professional's professional judgment and training and based on accepted standards of clinical practice consistent with the scope of his or her practice under the Medical Practice Act of 1987, the Nurse Practice Act, or the Physician Assistant Practice Act of 1987. HB4664 Enrolled LRB102 24218 AMQ 33447 b Public Act 102-1117 An advanced practice registered nurse or physician assistant as defined in this Act may perform aspiration

abortion procedures that do not require general anesthesia, consistent with their training and standards of clinical practice and, if applicable, consistent with any collaborative agreement.

Documentation of qualifications, training, work experience would be collected and evaluated the same way this is done for physicians on the Standard Illinois Health Care Professional Credentialing (or recredentialing) and Business Data Gathering Form

Effects on medical care: There would only be positive effects on the already high quality patient care and the high standards to which the facility holds the medical staff. Inclusion of more qualified team members on a medical staff only improve patient care. Each medical staff member would be privileged for surgical procedures which are appropriate to their training, experience and skill level.

Benefits for Hope Clinic: The change would allow Hope Clinic to significantly increase the number of available qualified providers at the facility – which is critical to continued quality patient care. The patient volume at Hope Clinic continues to increase as restrictions on abortion across the country are enacted. Restrictions on providers by employers and hospitals continues to increase, as well, which limits the available providers in the local area.

Illinois is supportive of the efforts of medical providers in the state to increase capacity for abortion care. Public Act 102-1117 (January 2023) describes “Temporary permits for health care” which includes physicians, advanced practice registered nurses and physician assistants and is clearly intended to address the current shortage of providers of abortion care in this state. (*Referenced below*)

REQUEST #3

Section 205.530 Operative Care

- c) Examination of Removed Tissues
 - 1) All tissues removed during surgery, except tissues and materials exempted under subsection (c)(3), shall be examined by a consulting pathologist, who shall provide a written report of the examination to the attending physician.
 - 2) A copy of the pathology report shall be filed in the patient's clinical record within seven days after removal of the tissue.

Current Hope Clinic policy is for all tissue be sent to a pathologist for review in compliance with this regulation.

Variance Requested: All tissues removed during first and second trimester abortion at Hope Clinic shall undergo a gross tissue examination by a qualified provider on the medical staff who shall document the findings in the medical record. If microscopic or further gross examination is recommended by this qualified provider based on the tissue examination or medical history, the tissue will be sent to a consulting pathologist.

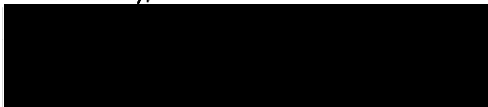
Explanation: All providers that are qualified to provide first or second trimester abortion care are also qualified to conduct a gross examination of the routine tissue removed during this procedure. At Hope Clinic this has been the current standard practice for over 10 years. In review of the last 5 years, the pathology reports obtained from the consulting pathologist have added no level of detail or change in patient management above that already recommended by the qualified provider. The facility has continued to also send all tissue to a consulting pathologist solely to comply with this regulation. It has become increasingly difficult to find organizations and pathologists that can examine tissue after

abortion procedures. This regulation is very beneficial when microscopic exam is required on multiple different types of tissues in most ASC settings. At Hope Clinic 99% of specimens are post-abortion tissue requiring gross examination only. Preparing, adding fixative and sending these specimens out to a consulting pathologist for a repeat gross examination is a completely unnecessary step for this facility. *Effects on Medical Care:* Only positive effects would be predicted and with less waste of staff time and costs. Prior to high quality ultrasound imaging, thorough pathology exam by a pathologist was necessary to detect conditions such as ectopic pregnancy. Appropriate use of pre, intra and post operative ultrasound combined with immediate tissue examination decrease undiagnosed ectopic and incomplete abortion risks. The consulting pathologist report has not improved medical care in these cases.

Benefits to Hope Clinic: To focus on sending medically appropriate cases to a consulting pathologist for review. To have options for various pathology partners if the facility is sending a lower volume of abortion related tissue for examination. To decrease wasted staff time and costs sending out already reviewed and reported normal pathology specimens for a second gross review and report.

Please review and consider these variance requests. More information or explanation can be provided at anytime upon request.

Sincerely,



Erin King ,MD
Executive Director
Hope Clinic

Reference:

Public Act 102-1117

225 ILCS 60/66 NEW

Sec. 66. Temporary permit for health care. (a) The Department may issue a temporary permit to an applicant who is licensed to practice as a physician in another state. The temporary permit will authorize the practice of providing health care to patients in this State if all of the following apply: (1) The Department determines that the applicant's services will improve the welfare of Illinois residents and non-residents requiring health care services. (2) The applicant has graduated from a medical program officially recognized by the jurisdiction in which it is located for the purpose of receiving a license to practice medicine in all of its branches, and maintains an equivalent authorization to practice medicine in good standing in the applicant's current state or territory of licensure; and the applicant can furnish the Department HB4664 Enrolled LRB102 24218 AMQ 33447 b Public Act 102-1117 with a certified

letter upon request from that jurisdiction attesting to the fact that the applicant has no pending action or violations against the applicant's license. The Department will not consider a physician's license being revoked or otherwise disciplined by any state or territory based solely on the physician providing, authorizing, recommending, aiding, assisting, referring for, or otherwise participating in any health care service that is unlawful or prohibited in that state or territory, if the provision of, authorization of, or participation in that health care, medical service, or procedure related to any health care service is not unlawful or prohibited in this State. (3) The applicant has sufficient training and possesses the appropriate core competencies to provide health care services, and is physically, mentally, and professionally capable of practicing medicine with reasonable judgment, skill, and safety and in accordance with applicable standards of care.

775 ILCS 55/1-25

- (a) A health care professional may provide abortion care in accordance with the health care professional's professional judgment and training and based on accepted standards of clinical practice consistent with the scope of his or her practice under the Medical Practice Act of 1987, the Nurse Practice Act, or the Physician Assistant Practice Act of 1987. HB4664 Enrolled LRB102 24218 AMQ 33447 b Public Act 102-1117 An advanced practice registered nurse or physician assistant as defined in this Act may perform aspiration abortion procedures that do not require general anesthesia, consistent with their training and standards of clinical practice and, if applicable, consistent with any collaborative agreement.

Glenn, Stephanie M.

From: Erin King <erking@hopeclinic.com>
Sent: Monday, April 3, 2023 5:57 AM
To: Glenn, Stephanie M.
Subject: Re: [External] ASC Regulation Variance Question
Attachments: Hope Clinic_Variance Request 4-3-23.pdf

Stephanie,

Please see attached information in follow up to our earlier email exchange about Hope Clinic's request for a variance in policy from the ASC Regulations.

Let me know what additional information you need or what questions I can answer. Request #1 and #2 are much more urgent than Request #3.

Sincerely,

Erin King, MD (she/her)

Executive Director

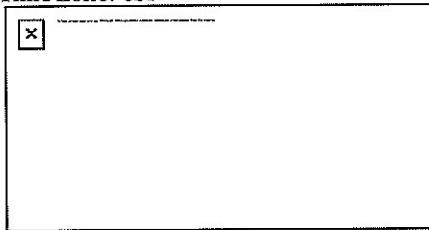
Hope Clinic

(618) 451-5722 ext. 329

618-451-9092 (fax)

erking@hopeclinic.com

Time Zone: CST



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On Fri, Feb 24, 2023 at 11:58 AM Erin King <erking@hopeclinic.com> wrote:

Stephanie,

Thank you for your quick response. Yes, will get this information organized and back to you as soon as possible.

Erin

Erin King, MD (she/her)

Executive Director

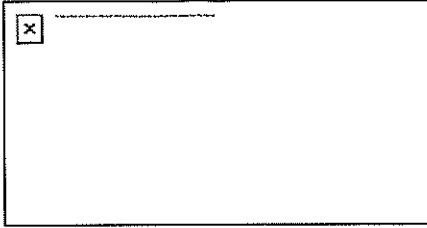
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On Fri, Feb 24, 2023 at 11:25 AM Glenn, Stephanie M. <Stephanie.Glenn@illinois.gov> wrote:

Hi Erin,

Can you please elaborate a little more? Myself or the Division Chief, Karen Senger, will most likely be the ones helping. Can you list the regulation you are wanting a variance on and what that variance is. Give an explanation as to how, if granted, this variance will help with operations, etc. or why the variance is needed.

Thanks,

Stephanie M. Glenn, RPh

Assistant Division Chief

Division of Health Care Facilities and Programs

Illinois Department of Public Health

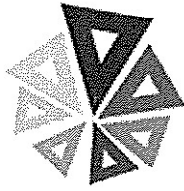
525 West Jefferson St., 4th Floor

Springfield, IL 62761

stephanie.glenn@illinois.gov

P-217-782-0850 F-217-782-0382

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**Diversity,
anti-Racism,
& Equity
Campaign**

ILLINOIS DEPARTMENT OF
PUBLIC HEALTH

From: Erin King <erking@hopeclinic.com>
Sent: Friday, February 24, 2023 11:18 AM
To: Glenn, Stephanie M. <Stephanie.Glenn@Illinois.gov>
Subject: [External] ASC Regulation Variance Question

Stephanie,

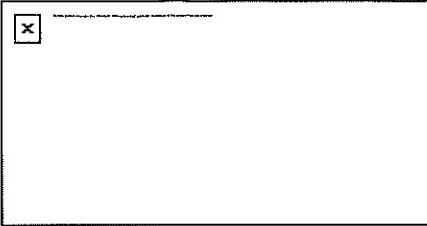
I am writing you to get connected with the correct person in your office to learn about applying for a "variance" from an ASC Regulation. I am not sure I am using the correct terminology - but using "variance" to define a difference from the usual ASC Regulation secondary to urgent conditions which make compliance more difficult and should not impact patient safety, etc..

Hoping this sounds like something you are familiar with a process for and can point me in the right direction.

Best

Erin

Erin King, MD (she/her)
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