New Jersey Department of Health

Division of Certificate of Need & Licensing

LICENSE

PLANNED PARENTHOOD OF NCSNJ

Pursuant to N.J.S.A. 26:2H-1 et seq.,

which is hereby licensed to operate

PLANNED PARENTHOOD OF NORTHERN, CENTRAL & SOUTHERN

1171 ELIZABETH AVENUE - ELIZABETH, NJ 07201

AMBULATORY CARE FACILITY - SATELLITE

consisting of:

Services:
Family Planning - Satellite

Parent/License# : ***PLANNED PARENTHOOD OF NORTHERN, CENTRAL & SOUTHERN/71472***

License #: **72038**
Effective: **May 1, 2022**
Expires: **April 30, 2023**
Issued: **April 12, 2022**

THE GREAT SEAL OF THE STATE OF NEW JERSEY

Judith M. Persichilli

Judith M. Persichilli
Commissioner

MUST BE POSTED IN A CONSPICUOUS PLACE IN THE FACILITY
THIS LICENSE IS NOT TRANSFERABLE, APPLIES ONLY TO THE ABOVE LOCATION, AND TERMINATES ON NOTICE BY THE DEPARTMENT

State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 358
TRENTON, N.J. 08625-0358
www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

JUDITH M. PERSICHILLI, RN, BSN, MA
Commissioner

April 12, 2022

Ms. TRISTE BROOKS

PLANNED PARENTHOOD OF NORTHERN, CENTRAL & SOUTHERN
1171 ELIZABETH AVENUE

ELIZABETH,NJ 07201

RE: Facility#: NJ72038/ License#: 72038

License Renewal

Dear Ms. TRISTE BROOKS:

Enclosed please find the official license for your health care facility, authorizing continued operation for the next twelve month period. The license must be posted in a conspicuous place in the facility. The license may not be transferred or assigned without the prior approval of the Department.

We appreciate your ongoing efforts to participate as a long term health care provider in NJ. In accordance with N.J.S.A. 26:2H-5, the Department may conduct surveys of the facility to ascertain compliance with all regulatory requirements. The renewal is valid for a one year period, unless revoked or suspended for failure to meet licensure requirements.

Please include the official name of the facility, the license number and contact email(s) on all correspondence if available.

If you have any questions about the license or licensure process, please call this office at (609)292-6552.

Sincerely,

Michael J. Kennedy, J.D.
Executive Director
Certificate of Need and Licensing
New Jersey Department of Health

Your creditCard transaction has been successfully processed. The transaction confirmation number is 163677282 . Please print this page for your record.

Credit Card Payment

Payer Information

Last Name:
BROOKS

First Name:
TRISTE

Contact Information

* Telephone Phone: 9733494803
* Email Address: jarret.allende@ppgnnj.org

Payment Information

* Application Payment Amount: $875.00
* Payment Including Service Fee: $893.00

Please PRINT this confirmation for your records.
If your registration requires completion of an application please use RETURN button to open the application and follow the instruction.
Otherwise use RETURN button to go back.

Note: Do not click on the back button.

PRINT RETURN

Facility Data Sheet

Facility Detail

Facility:	Planned Parenthood of Northern, Central and Southern New Jersey, Inc.	Facility ID:	NJ72038
Type:	AMBULATORY CARE FACILITY - SATELLITE	Tracking:	LR-72038-21194
License#:	72038	License Expires:	4/30/2022 12:00:00 AM

Payment Information

Renewal Fees:	$475.00	Inspection Fees:	$400.00	Other Fees:	$0.00	Total Due:	$875.00

Facility Information

Address:	1171 ELIZABETH AVENUE, ELIZABETH, NJ, 07201	Medicare#:	
County:	UNION	Medicaid#:	
Telephone:	(973) 879-1306	New Telephone:	
Fax:	(908) 353-6822	New Fax:	
Email:	amy.raspatello@ppgnnj.org	New Email:	

Mailing Address

Address:	1171 ELIZABETH AVENUE	New Address:	
City:	ELIZABETH	New City:	
State:		New State:	
Zip:	07201	New Zip:	

Emergency Contact

Name:	Amy Raspatello	New Name:	
Phone:	(973) 879-1306	New Phone:	
Fax:		New Fax:	
Email:	amy.raspatello@ppgnnj.org	New Email:	

Administrator

Salutation:	Ms	New Salutation:	
First Name:	TRISTE	New First Name:	
Middle Name:	A	New Middle Name:	
Last Name:	BROOKS	New Last Name:	
Title:		New Title:	
Phone Number:		New Phone Number:	
Email:		New Email:	
Current Primary:	Yes	New Current Primary:	
Start Date:	11/02/2009	New Start Date:	
End Date:		New End Date:	

Owner Detail

Company Name:	PLANNED PARENTHOOD OF NCSNJ		
Type:	AMBULATORY CARE FACILITY - SATELLITE	Business Type:	
Company Tax ID:		Company Tax ID:	
Address:	196 SPEEDWELL AVENUE	New Address:	

Phone Number:	(973) 539-9580	New Phone Number:	
Fax Number:		New Fax Number:	
Email:		New Email:	

Facility Officers/Principals Name and Ownership Detail

VINITA JETHWANI		0.00%
RALPH PADILLA		0.00%
JOSHUA S SAKS	BRD MEMBER	0.00%
PATRICK STOVER	CHAIR	0.00%
PATRICIA COOK		0.00%
KATHERINE E KLEEMAN	CHAIR	0.00%
BENN MEISTRICH	1ST VP	0.00%
STEPHANIE A FISHER	VICE CHAIR	0.00%
CONNIE NEWMAN	SECRETARY	0.00%
MICHAEL ROEMER	TREASURER	0.00%
JOAN GOTTI	GOV CHAIR	0.00%
SHELDEN PISANI	BRD MEMBER	0.00%
MARC BRAHANEY	2ND VP	0.00%
KEVIN LAU	ESQ	0.00%

Bed / Services / Slots *Facility ID: NJ72038* *Tracking: LR-72038-21194*

Services & Designations:

Family Planning - Satellite

Related Facilities

Name	License#

Current Accreditation	New Accreditation
Accrediting Body:	Accrediting Body:
Effective Date:	Effective Date:
Expiration Date:	Expiration Date:
Hospital Attestation :	Hospital Attestation (Yes/No):
Hospital Attestation Letter Date:	Hospital Attestation Letter Date:
Deem :	Deem (Yes/No):

Note: Please include the accreditation certificate(s) and hospital attestation letter, if applicable.

LICENSE RENEWAL QUESTIONNAIRE

AMBULATORY CARE FACILITY - SATELLITE

License#: 72038 Expires: NJ72038 Ref#: LR-72038-21194

Please answer the following questions (attach additional sheets if necessary)

1. Have any of the principals of the operating entity ever applied, directly or indirectly,for health care facility approval in New Jersey or any other state,which was denied or revoked ? NO (Yes/No) If Yes, indicate whom and give details:

2. Do any of the principals of the operating entity have an ownership, operational or management interest in any other licensed health care facility in New Jersey, or any other state ? NO (Yes/No) If Yes, explain the nature of the interest and give name and address of each facility :

3. Have any principals of the operating entity ever been found guilty of a criminal or administrative charge of resident/patient fraud,abuse and/or neglect ? have any of these ever been indicted for the same charge ? NO (Yes/No) If Yes, explain in detail:

4. Have any principals of the operating entity ever been indicted for or convicted of a felony crime ? NO (Yes/No) If Yes, indicate whom and give details

CERTIFICATION

The applicant certifies:
1) that all information contained in this application and attachments is true and correct, to the best of his/her knowledge and belief, and that willful misrepresentation of these facts may make the applicant subject to civil penalties;
2) that the application has been duly authorized by the governing body of the applicant;
3) that the facility has been and will be operated in accordance with applicable licensing requirements;
4) that the facility is not suspended, debarred , or otherwise excluded for any reason from entering into the covered transaction; and
5) that the facility is in compliance with the requirements of Section 6032 of The Federal Deficit Reduction Act.

Name of authorized individual completing form (print or type):

Print Name: Jarret Allende Title: VP Medical Services

Signature: Date: 3/22/22

State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 358
TRENTON, N.J. 08625-0358
www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

JUDITH M. PERSICHILLI, RN, BSN, MA
Acting Commissioner

May 11, 2022

VIA ELECTRONIC & FIRST-CLASS MAIL

Triste Brooks, Co-CEO
Cory Neering, Co-CEO
Planned Parenthood of Northern, Central and Southern NJ, Inc.
1171 Elizabeth Avenue
Elizabeth, NJ 07201

Re: Waiver # 8426 – Approved with Conditions
N.J.A.C. 8:43A-19.1; 2018 FGI sections 2.1 and 2.13
Planned Parenthood of Northern, Central and Southern New Jersey
1171 Elizabeth Avenue
Elizabeth, New Jersey 07201
License # 72038
Provision of Minor Gyn Procedures in (2) Exam Rooms (#115, #108)

Dear Ms. Brooks and Mr. Neering:

It has been brought to the Department of Health's (Department) attention that a response to the waiver forthcoming was not received. Therefore, please refer below to the Department's response to your request for a waiver from the physical plant requirement in N.J.A.C. 8:43A-19, Licensing Standards for Ambulatory Care Facilities, and sections 2.1 and 2.13 of the 2018 Facility Guidelines Institute (FGI) Guidelines for Design and Construction of Health Care Facilities regarding the provision of minor gynecological (gyn) procedures in (2) Exam Rooms #115, and #108 at Planned Parenthood of Northern, Central and Southern New Jersey facility (PPNCSNJ), located at the above address in Elizabeth, New Jersey.

You are requesting the above waiver so that PPNCSNJ can provide limited minor gynecological (gyn) procedures; colposcopy, LEEP, endometrial biopsy, and cryotherapy, in examination room one (#115) & examination room two (#108) in the Elizabeth facility.

N.J.A.C. 8:43A-19.1- Physical Plant and Functional Requirements requires that new buildings, alterations and additions to existing buildings for freestanding ambulatory care facilities shall conform with New Jersey Construction Code, N.J.A.C. 5:23, and construction guidelines.

You indicate that PPNCSNJ will meet all applicable clinical and infection control standards to provide the above limited minor gynecological procedures, in Examination Room 1 (#115), which has 112 square feet (s.f.) and an adjacent patient toilet, and Examination Room 2 (#108), which has 129 s.f. and located across the hall from a patient bathroom.

After consultation with staff from the Department, including the Department's Architect reviewer, the Department has decided to approve your request for a waiver from the physical plant requirement in N.J.A.C. 8:43A-19 and FGI Guidelines' section 2.13-3.8.13 with the following conditions:

1) Procedures to be provided in Examination Room 1 (#115) & Examination Room 2 (#108) shall be limited to minor gyn procedures- colposcopy, LEEP, endometrial biopsy, and cryotherapy and the administration of topical, local and para-cervical block anesthesia only.

2) A policy and procedure shall be implemented and established in the facility's policy and procedure manual to address the above in Examination Room 1 (#115) & Examination Room 2 (#108).

3) The above waiver approval shall be limited only to PPNCSNJ's facility, located at 1171 Elizabeth Avenue, Elizabeth, New Jersey.

As with all waivers granted by the Department, a waiver may be rescinded at any time if the waiver has any negative impact on patients. Please be advised that this waiver becomes void upon any regulations and/or guidelines having an impact on the physical plant, including those incorporated by reference.

Please be advised that the owner/operator/licensee is responsible for satisfying all other applicable State, Federal and Local physical plant regulations related to the proposed project, including, NFPA 101 Life Safety Code (2012), all as amended and supplemented. The plans review approved herein is based on compliance with State requirements only. The Department takes no position on compliance with the Centers for Medicare and

Medicaid Services' Life Safety Code requirements. Thus, this letter shall not be construed as satisfying all these regulations. In addition, this approval is not intended to preempt in any way any municipality's authority to regulate land use within its borders. Therefore, this letter shall not be used to represent that the Department has made any findings or determinations relative to use any specific property.

Please also be advised that the aforementioned waiver is for the use of the licensed operator at the above location only. If there is any new construction, renovation, or alterations to the physical plant, which may affect the waivered condition, or changes in the services as originally presented, this waiver will no longer be valid, and the facility will be required to resubmit their request to the Department for re-evaluation. Lastly, be further advised that should the facility transfer ownership upon Department authorization, the new owner/operator must request continuation of this waiver.

Please be advised that this approval is limited to the proposal as presented and reviewed. The application, related correspondence, and any completeness questions and responses are incorporated and made a part of this approval. The Department in approving this application has relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. If material facts have not been disclosed or have been misrepresented, the Department may take administrative regulatory action to rescind the approval or refer the matter to the Office of the Attorney General. The Department in approving this application has relied solely on the facts and information presented to us.

Please be advised that any approval granted by the Department relates to certificate of need and/or licensing requirements only and does not imply acceptance by a reimbursing entity. This letter also is not intended as an approval of any arrangement affecting reimbursement or remuneration involving claims for health care services.

Furthermore, regardless of any management arrangement addressing the operation of the facility between the licensee and any other entity, the licensee is responsible for financial, operational and management control. All health services provided by the facility and the revenue generated by the facility from providing these services is the responsibility of the licensee.

If you have any questions regarding this matter, you may contact Theresa D'Errico at theresa.derrico@doh.nj.gov .

Sincerely,

Michael J. Kennedy, J.D.
Executive Director
Division of Certificate of Need and Licensing
New Jersey Department of Health

C:

K. Hanson (DOH)
L. Alexopoulos (DOH).
Ms. Kiernan (DOH)
Ms. Gorski-Galla (DOH)
Ms. Sousa (DOH)
Ms. Tenzer (DOH)
Licensing Intake (DOH)
Mr. Lohman (DOH)
T. D'Errico (DOH)
E. Barrow (DOH)

Email:

Fogg, Robert J.- rfogg@archerlaw.com
triste.brooks@ppgnnj.org
cory.neering@ppgnnj.org

New Jersey Department of Health
Office of Certificate of Need and Healthcare Facility Licensure
P.O. Box 358
Trenton, NJ 08625-0358 EB

W-2426

RECEIVED
OCT 21 2021
HEALTH FACILITIES EVAL. & LIC.
CN & Health Care Facility Licensing

APPLICATION FOR WAIVER

(Requests for more than one waiver may not be combined. An Application for Waiver form must be completed for each waiver requested).

CN Ref. #	DCA Ref. #	Facility ID # (if currently licensed)
n/a	**n/a**	**72038**

Name and Address of Facility:

Planned Parenthood of Northern, Central and Southern New Jersey, Inc.
1171 Elizabeth Avenue
Elizabeth, NJ 07201

Name, Address and Telephone Number of Owner, Chief Executive Officer (CEO), Chief Operating Officer (COO), or Administrator of the Existing or Proposed Facility:

Triste Brooks and Cory Neering, Co-CEO's
PPNCSNJ
196 Speedwell Avenue
Morristown NJ 07960
973-539-9580 ext 151

Name, Address and Telephone Number of Architect:

n/a

The owner, CEO, COO or Administrator of the existing or proposed health care facility hereby applies for a waiver to the following regulation (identify regulation by name, code citation (if applicable) and date (if applicable):

N.J.A.C. 8:43A-19.1 Physical Plant and Functional Requirements.
(a) New buildings and alterations and additions to existing buildings for freestanding ambulatory care facilities shall conform with the New Jersey Construction Code, NJAC 5:23, and the "construction guidelines".

APPLICATION FOR WAIVER (continued)

A. Provide the following information for each rule or part of rule for which a waiver is being requested. Attach additional sheets as necessary.

1. Restate rule or part of rule for which a waiver is being requested and identify the specific rule citation.

PPNCSNJ seeks a waiver from the Department's interpretation that the FGI Guidelines for Design and Construction of Outpatient Facilities at standard 2.1-3.2.1.2 do not permit PPNCSNJ to perform certain basic gynecological procedures, such as colcoscopies and LEEP's, in an Examination Room. See attached listing of minor gynecolegical procedures that are the subject of this waiver request. Note that the list of basic gynecological medical services provided by PPCNSNJ at this location is very extensive and they have not therefore been listed.

2. Describe the reasons for requesting a waiver, including a statement of the type and degree of hardship that would result upon compliance.

PPNCSNJ requests a waiver of this interpretation of the FGI standards as compliance will pose a hardship and minimize access to essential gynecological health services. Restricting and scheduling all colposcopies, LEEP's, and endometrial biopsies in the single Procedure Room at the Elizabeth facility will reduce PPNCSNJ's capacity to schedule and provide these services. This will minimize access by undeserved populations to these essential women's health services that are within the scope of a Family Planning agency.

3. Describe an alternative proposal to ensure patient safety.

PPNCSNJ will continue to safely meet all applicable clinical standards for providing minor GYN procedures in an Exam Room. PPNCSNJ clinician's will utilize a Procedure Room for cases that involve invasive incisions into normally sterile body cavities requiring higher environmental controls, or involving additional instrumentation and equipment requiring a larger room. Examination room #108 (Exam #2) will be utilized for GYN procedures, which has 129 square feet, and is directly across the hall from a patient bathroom. In addition, Room 114 ("Exam 1") will be used for cases as needed, adjacent to the patient toilet and has 112 sf of space. Each exam room exceeds the 80 sf minimum space required at FGI Section 3.1-3.2.2.2 (1).

4. Is documentation attached to support the waiver request?

☐No ☒Yes (Identify):

ACOG research article: "Consensus Guidelines for Facilities Performing Outpatient Procedures" concluding that increasing the size of examination rooms beyond those in effect for general medical offices is not justified for facility-based gynecological procedures and related procedures.

B. Is the project currently under review by the Department of Community Affairs, Health Care Plan Review?

☒No ☐Yes (Identify DCA Reviewer)

C. Is the request for a waiver based on plan review comments by the Department of Community Affairs.

☒No ☐Yes (Attach Comments)

Name of Owner, CEO, COO or Administrator	Title
Triste Brooks	**CEO**
Signature of Owner, CEO, COO or Administrator	Date 10/18/21

ATTACHMENT C

Minor Gynecological Procedures to be Performed in Examination Rooms

1. Colposcopy
2. Loop Electrosurgical Excision Procedure (LEEP)
3. Endometrial Biopsy
4. Cryotherapy

ATTACHMENT D

Consensus Guidelines for Facilities Performing Outpatient Procedures

Evidence Over Ideology

Barbara S. Levy, MD, Debra L. Ness, MS, and Steven E. Weinberger, MD

In policy and law, regulation of abortion is frequently treated differently from other health services. The safety of abortion is similar to that of other types of office- and clinic-based procedures, and facility requirements should be based on assuring high-quality, safe performance of all such procedures. False concerns for patient safety are being used as a justification for promoting regulations that specifically target abortion. The Project on Facility Guidelines for the Safe Performance of Primary Care and Gynecology Procedures in Offices and Clinics was undertaken by clinicians, consumers, and representatives from accrediting bodies to review the available evidence and guidelines that inform safe delivery of outpatient care. Our overall objective was to develop evidence-informed consensus guidelines to promote health care quality, safety, and accessibility. Our consensus determined that requiring facilities performing office-based procedures, including abortion, to meet standards beyond those currently in effect for all general medical offices and clinics is unjustified based on an analysis of available evidence. No safety concerns were identified.

(Obstet Gynecol 2019;133:255–60)
DOI: 10.1097/AOG.0000000000003058

Government has a legitimate role in protecting the public by establishing standards and requirements for health care provider licensure. However, many proposed laws and regulations at both the state and national levels lack scientific evidence to support any safety concerns defining a need or benefit to patients resulting from those requirements.[1] Some of these laws apply broadly to outpatient settings in which surgery, procedures, or certain levels of sedation are offered; others apply specifically to abortion. They target clinics and facilities that provide medication-induced as well as procedural abortion services. Currently, 16 states have requirements for licensing abortion clinics similar to those for ambulatory surgical centers, whereas 19 require specific dimensions for procedure rooms and corridors.[2] Additionally, 21 states require abortion clinic providers to maintain a relationship with a local hospital.[2] Laws of this nature can have a profound effect on access to abortion, as exhibited by the decline in Texas from 46 clinics in 2011 to 28 clinics in 2014 after passage of onerous facility restrictions.[3] By 2014, 90% of U. S. counties, in which 39% of reproductive age women live, had no clinics providing abortion care.[3]

From the American College of Obstetricians and Gynecologists and National Partnership for Women & Families, Washington, DC; and the American College of Physicians, Philadelphia, Pennsylvania.

Supported by staff at the American College of Obstetricians and Gynecologists, the Advancing New Standards in Reproductive Health (ANSIRH) program at the University of California, San Francisco, and the National Partnership for Women & Families. Support for the costs of the Project was provided by these organizations, as well as by an anonymous U.S.-based, 501(c)(3), charitable foundation. The foundation had no influence on, or involvement in, the Project process, meeting, document creation, or other activities. In-kind support for the Project was provided by the members of the Procedures Working Group and the organizations represented on the planning committee.

The authors thank Bonnie Scott Jones and Molly Battistelli, of Advancing New Standards in Reproductive Health (ANSIRH), University of California, San Francisco, as well as Sarah Horvath, MD, and Jennie Shaw, MPH, American College of Obstetricians and Gynecologists, for their assistance in the drafting process.

The Procedures Working Group list is in Appendix 1, available online at http://links.lww.com/AOG/B234.

Each author has confirmed compliance with the journal's requirements for authorship.

Corresponding author: Barbara S. Levy, MD, Vice President, Health Policy, American College of Obstetricians and Gynecologists, 409 12th Street SW, Washington, DC 20024-2188; email: blevy@acog.org.

Financial Disclosure
The authors did not report any potential conflicts of interest.

ISSN: 0029-7844/19

Procedures are a critical part of both primary care and gynecologic care. Offering procedures in office and clinic settings has the potential to significantly improve patient care, access, affordability, and experience. The American College of Obstetricians and Gynecologists defines a procedure as "a short interventional technique that includes the following general categories:[4]

- Nonincisional diagnostic or therapeutic intervention through a natural body cavity or orifice
- Superficial incisional or excisional diagnostic or therapeutic intervention that does not involve repair or significantly alter morphology
- Device placement into a natural cavity
- Subcutaneous implant
- Injections

The American College of Obstetricians and Gynecologists states that the classification of an intervention as a "procedure" should be based on the nature of the intervention itself and not on the location at which the procedure is performed.

The Project on Facility Guidelines for the Safe Performance of Primary Care and Gynecology Procedures in Offices and Clinics (the Project) was undertaken to support evidence-informed policy regarding the provision of procedures in primary care and gynecology offices and clinics. The Project brought together a broad group of clinicians, consumers, and representatives from accrediting bodies to review available evidence and clinical practices. The goal of the Project was to articulate evidence-informed facility guidelines that would further health care quality, safety, affordability, and patient experience without imposing unjustified burdens on patients' access to care or on clinicians' ability to provide care within their scope of practice.

The Project was led by a planning committee made up of representatives from the American College of Obstetricians and Gynecologists, the National Partnership for Women & Families, the American College of Physicians, the American Academy of Family Physicians, the American College of Nurse-Midwives, Nurse Practitioners in Women's Health, and the Society of Family Planning. Participants in the Project included health care professionals, advocates, and experts in care quality, accreditation, and the provision of primary and gynecologic care in office and clinic settings. From September 26, 2016, to July 11, 2018, the planning committee defined the scope of the Project, recruited a working group of experts and stakeholders ("Procedures Working Group"), and gathered and reviewed evidence. The Procedures Working Group then convened to discuss research evidence, provide expert opinion, and consider appropriate guidelines and practices. They engaged in an iterative, virtual drafting process for crafting a consensus document, solicited and considered public comments, and finalized the consensus guidelines (Fig. 1).

The planning committee defined the Project scope to address only facility factors (those relating to physical environment or office and clinic operations); it did not delve into matters of clinical practice or scope of practice. The Procedures Working Group then sought to define guidelines and accepted practices for facilities in which procedures are performed and to articulate new guidelines where appropriate, given the best available evidence. It did not seek to define which procedures may appropriately be performed in offices and clinics. The Procedures Working Group considered only offices and clinics providing procedures within primary care or gynecology; it did not consider facilities providing procedures in other practice areas. Further, it did not seek to articulate guidelines and accepted practices for the provision of sedation and anesthesia; the American

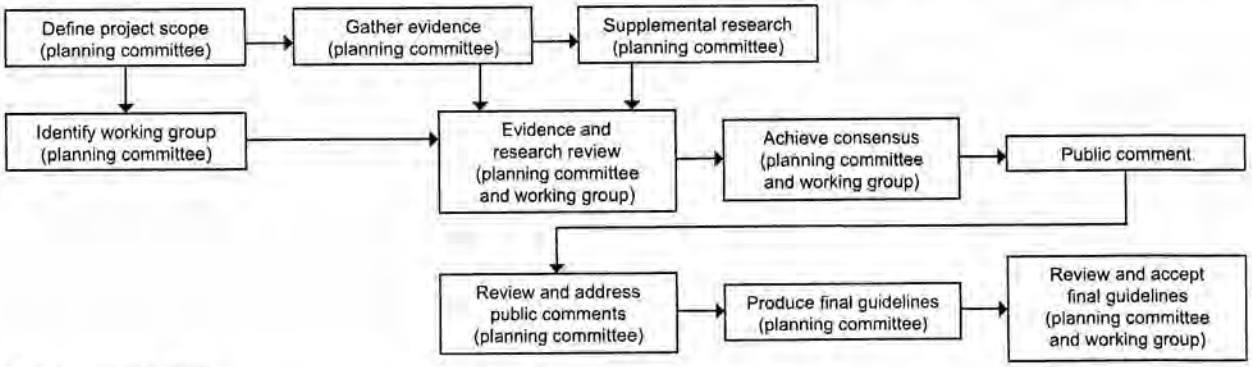

Fig. 1. Project flow.
Levy. Guidelines for Facilities Performing Outpatient Procedures. Obstet Gynecol 2019.

Society of Anesthesiologists has developed widely accepted guidelines in this area. The Procedures Working Group presumed that the applicable portions of those guidelines are followed by clinicians providing sedation and anesthesia in this setting.

The planning committee gathered available evidence regarding the effect of select facility factors on patient safety, care quality, and service availability for review by the Procedures Working Group. The facility factors selected by the planning committee (listed in Box 1) were chosen based on occurrence in existing laws and guidelines governing outpatient surgeries and procedures. The planning committee began the evidence-gathering process by seeking verbal input from a diverse set of experts about relevant evidence to consider. The individuals consulted by the planning committee (see list in Appendix 1, available online at http://links.lww.com/AOG/B234) in this regard included experts in patient safety, health service delivery and access, health care disparities, and health care facility design and construction. Because very little research exists regarding outpatient facility factors, the planning committee cast a wide net in gathering potentially relevant research; thus, some of the research considered comes from outside the area of primary care and gynecology procedures.

A systematic review undertaken by independent researchers served as the foundational research for the Project.[5] This study, which was conducted according to established systematic review standards and published in a peer-reviewed journal, examined the effects of outpatient facility type and specific facility characteristics on patient safety, patient experience, and service availability outcomes in non–hospital-affiliated outpatient settings. The systematic review sought to address two questions: 1) What is the effect of outpatient setting (ambulatory surgery center compared with office) on patient safety, experience, and service availability for outpatient procedures; and 2) What are the effects of particular facility characteristics (facility accreditation, emergency response protocols, clinician qualifications, physical plant specifications, and other policies) on those same outcomes? The authors concluded that existing evidence does not indicate a difference in patient safety for procedures across ambulatory surgery centers and offices. On the second question, the researchers concluded that there was not enough research on any of the facility characteristics to draw conclusions across studies but that there was a suggestion that requiring abortion providers to have hospital admitting privileges may result in decreased service availability for women seeking abortion.

Box 1. Facility Factor

- Emergency preparedness
  - Facility emergencies
  - Patient emergencies
- Biological material handling
- Physical plant specifications
  - Hall and doorway widths
  - Operating rooms
  - Procedure rooms
  - Separate clean and soiled sterilization rooms
  - Temperature and ventilation
- Clinician qualifications beyond licensing
- Other policies and procedures
  - Infection control
  - Patient satisfaction assessment
  - Peer review of clinicians
  - Preventive maintenance
  - Quality assurance
- Facility accreditation, licensing, or faculty accreditation and licensing

The planning committee supplemented these existing studies with three less formal research inquiries undertaken specifically for the Project.

1. First, the planning committee enlisted a researcher to review the literature for information about how facility laws affect access to health care services in offices and clinics. The researcher found limited published research on the topic, the bulk of which addressed three policy areas (the Mammography Quality Standards Act, the Clinical Laboratory Improvement Amendments, and state-level facility requirements governing the provision of abortion). The limited evidence available suggests that the effect of new facility regulation on patients' access to care depends largely on whether such regulation is attuned to patient and facility needs and includes measures to support facilities as they seek to come into compliance.
2. Second, to gain information about existing facility guidelines for outpatient facilities, researchers conducted a review and appraisal of existing facility guidelines. As few such guidelines exist, the researchers broadly surveyed guidelines for outpatient provision of any surgeries or procedures. The researchers evaluated the quality of guidelines they reviewed using both the Appraisal of Guidelines for Research & Evaluation II tool[6] and the Non-Research Evidence Appraisal Tool from the Association of periOperative Registered Nurses.[7] They then reviewed and summarized the contents of the five guidelines with the highest quality assessment scores.

3. Third, to determine whether any relevant public health or patient safety issues related to facility factors had been documented, research was undertaken to examine press releases, published guidance, and opinions from state medical boards and selected health professional organizations. This research found no documentation of any public health or patient safety issues related to facility factors in offices or clinics providing primary care or gynecology procedures.

At an in-person meeting, participants analyzed the available evidence, shared current accepted practices, and discussed whether any evidence of potential harms exists in six areas: emergency preparedness, biological material handling, physical plant specifications, facility accreditation and licensing, clinician qualifications beyond licensing, and other policies and procedures. Researchers examined outpatient accrediting body requirements and state facility laws for office and clinic settings to ensure inclusion. An iterative process then was used to reach consensus among Procedures Working Group members about current accepted practices, areas of possible concern, and the potential need for changes to current accepted practices in each area.

The Project produced consensus guidelines (Box 2) that will further evidence-informed facility practices and policies for primary care and gynecology procedures, including abortion. Feedback on the draft guidelines was solicited from stakeholders and members of the public via a public comment process from April 17, 2018 to May 13, 2018. The draft was posted on an interactive, public website that allowed for submission of comments, proposed edits, and additional evidence. Announcements of the public comment period were sent to health professional and health care organizations according to outreach processes commonly used in the development of clinical guidelines. The feedback provided during the public comment process was thoroughly reviewed and considered by the planning committee. Overall, the comments were supportive and indicated the guidelines were appropriate as written. In some cases, the planning committee made minor revisions or clarifications to the draft guidelines as appropriate and justified by the evidence. The Procedures Working Group reviewed the revised guidelines, gave feedback as necessary, and came to consensus on the content of the final guidelines.

Participants found no evidence of any patient safety or quality-of-care problems related to the examined facility factors in offices or clinics that

Box 2. Facility Guidelines

Facilities' policies, procedures, and supplies should be suited to the nature of the practice and procedures performed. In some facilities, appropriate policies, procedures, and supplies will be minimal. Solo or small practices that perform only occasional, limited procedures should assess which of the guidelines are appropriate to the practice given the procedures performed at the site.

Emergency Preparedness

- Facilities should establish written policies and procedures for managing facility emergencies (eg, natural disaster, fire) and patient emergencies (eg, vasovagal reaction, hemorrhage) and should conduct periodic drills and staff trainings on those policies and procedures. A formal transfer agreement with a hospital is not required because transfers are rare and hospitals are required to accept patients with emergent needs. Good communications in the event of a transfer and working relationships with facilities that may receive or refer patients are encouraged.
- Facilities should have a staff person trained in basic life support onsite when procedures are performed and have a person other than the clinician performing the procedure onsite to provide assistance, call for additional assistance, or transport to a hospital in an emergency.
- Facilities should maintain adequate supplies for basic life support and medications and equipment needed to treat emergencies that may occur with the procedures performed.
- Facilities should provide basic emergency lighting (eg, battery backup lighting, flashlights).
- Facilities should keep doorways and hallways free of obstructions that could impede exit by patients and staff or ingress by emergency personnel. Where the types and risks of procedures performed at the facility create a reasonable likelihood that patient transfer by stretcher may be needed, doorways and hallways in the path of egress should be sufficiently wide to permit passage by stretcher (note that this term includes chair stretchers, which can be maneuvered through typical office doorways and hallways).
- Facilities should provide wayfinding signage that is understandable to the patient population served.

Biological Material Handling

- Facilities should establish written policies and procedures for properly labeling, handling, and storing biological specimens to be sent to pathology or other laboratory. The decision of whether to send specimens for pathology evaluation is made by the clinician or on the basis of facility policies.
- Facilities should establish written policies and procedures for handling, storing, and disposing of hazardous materials in a manner that minimizes the risk of exposure and for reducing the risk of harm to individuals involved, should exposure occur. Tissue not sent to pathology should be disposed of in the same manner as other biological materials. Tissue used in research or commercial endeavors is subject to separate requirements not addressed in this document.

Box 2. Facility Guidelines

Biological Material Handling *(continued)*

- Facilities should conduct periodic staff training on the policies and procedures described.

Physical Plant Specifications*

- Facilities should consider patient privacy, confidentiality, and comfort in the design and flow of the facility.
- Facilities should perform procedures in examination rooms or procedure rooms adequate to accommodate the equipment and personnel involved in the procedure. Typical examination rooms are an adequate size for most procedures; a room larger than needed to accommodate the equipment and personnel involved in the procedure is neither necessary nor desirable.
- Facilities should have patients recover in the room in which the procedure was performed or in a separate recovery room or area. A separate recovery room is not required. Some procedures require no recovery time.
- Facilities should provide separate storage for clean and dirty supplies.
- If instruments are sterilized onsite, facilities should provide separate marked areas for soiled and clean instrument processing. Separate rooms for those functions are not required. Offsite sterilization services may also be used.
- Facilities should provide a source of emergency power for equipment if any of the procedures performed in the facility are ones in which a power loss during the procedure would threaten patient safety.
- Facilities should have onsite, and maintain in good condition, the equipment needed for the procedures performed.
- Facilities should use adequate heating, ventilation, and cooling systems. Systems typical for offices are adequate in this context; no special heating, ventilation, or cooling systems are needed.
- Facilities that store specimens or medications requiring refrigeration should provide separate refrigerated storage for each.

Facility Accreditation and Licensing

- Procedures should be provided in facilities that meet current accepted practices. Such accepted practices do not require facility accreditation or facility licensing.

Clinician Qualifications Beyond Licensing

- Facilities should ensure that clinical staff are trained in the procedures performed, equipment used in the facility, basic life support, cultural sensitivity, and any requirements governing the facility with regard to accommodations to facilitate safe and appropriate access to health services for individuals with disabilities or other conditions, including limited English proficiency. Although some facilities will have no need for nursing staff, facilities should ensure that any clinical duties requiring nursing care are staffed appropriately.

Box 2. Facility Guidelines

Clinical Qualifications Beyond Licensing *(continued)*

- Facilities should designate a clinician responsible for ensuring that clinicians who perform procedures at the facility have established competence in those procedures. Such competence may be established through any of a variety of training, education, and assessment activities (which may be specified by the facility, a professional organization, or specialty). Neither board certification nor hospital privileges are required.

Other Policies and Procedures

- Facilities should establish written policies and procedures for infection control, conduct periodic staff training on those policies and procedures, and implement a plan to monitor compliance.
- Facilities that perform procedures on more than an occasional basis should establish a written quality improvement plan that includes recording and reviewing available facility data on select adverse outcomes related to procedures performed and ways to act on information gained.
- Facilities should establish a written policy and schedule for checking equipment functioning.
- Facilities should establish a written policy and schedule for managing medication inventory.

*We have included some physical plant–related matters in the guidelines for emergency preparedness.

provide primary care and gynecology procedures. Given the available evidence, the Procedures Working Group concluded that there is insufficient research to find that particular facility factors have either a positive or negative effect on patient safety or experience (very little research has been conducted in these areas, and the findings from that limited research are not definitive). The Procedures Working Group also noted that research suggests the possibility that some facility requirements may result in decreased service availability.[5] These findings mirror those of the National Academies of Sciences, Engineering, and Medicine, which recently published their report, "The Safety and Quality of Abortion Care in the United States." They, too, conducted a comprehensive literature review. Using a quality lens and the six dimensions of care quality–safety, effectiveness, efficiency, timeliness, equity, and patient-centered care–the authors found no evidence that regulations targeted at abortion care improved safety. They did find that other aspects of quality care delivery were negatively affected by those regulations–specifically, access to care, timeliness, and the availability of local, qualified providers.[8,9]

CONCLUSIONS

Requiring facilities that perform office-based procedures, including abortion, to meet standards beyond those currently in effect for all general medical offices and clinics is unjustified based on this thorough review and analysis of available evidence; safety concerns were not identified in any area of study.

The consensus guidelines developed by committee experts and stakeholders through systematic review of the literature, provide an evidence-informed basis for evaluating legislation and regulations that use patient safety as a justification for restrictive and ideologically driven policies. This research provides the evidence base to conclude that additional regulation for outpatient procedures, including abortion, has no documented necessity. Targeting specific procedures based on ideology rather than evidence sets a dangerous precedent for the regulation of medicine. It is essential for all health care providers and advocates to evaluate new and proposed facility requirements according to available evidence as outlined in this document. When such regulations are deemed unnecessary, it is incumbent on these same experts to oppose them. Enacting superfluous facility requirements is politics, not public safety.

REFERENCES

1. Weinberger SE, Lawrence HC, III, Henley DE, Alden ER, Hoyt DB. Legislative interference with the patient-physician relationship. N Engl J Med 2012;367:1557–9.
2. Guttmacher Institute. Targeted regulation of abortion providers. Available at: https://www.guttmacher.org/state-policy/explore/targeted-regulation-abortion-providers. Retrieved September 20, 2018.
3. Guttmacher Institute. State facts about abortion. Texas. Available at: https://www.guttmacher.org/fact-sheet/state-facts-about-abortion-texas. Retrieved September 20, 2018.
4. American College of Obstetricians and Gynecologists. Definition of "procedures" related to obstetrics and gynecology: position statement. Available at: https://www.acog.org/Clinical-Guidance-and-Publications/Position-Statements/Definition-of-Procedures-Related-to-Ob-Gyn. Retrieved September 20, 2018.
5. Berglas NF, Battistelli MF, Nicholson WK, Sobota M, Urman RD, Roberts SCM. The effect of facility characteristics on patient safety, patient experience, and service availability for procedures in non-hospital-affiliated outpatient settings: a systematic review. PLoS One 2018;13:e0190975.
6. Brouwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al. AGREE II: advancing guideline development, reporting and evaluation in health care. Can Med Assoc J 2010;182:E839–42.
7. Spruce L, Van Wicklin SA, Hicks RW, Conner R, Dunn D. Introducing AORN's new model for evidence rating. AORN J 2014;99:243–55.
8. National Academies of Sciences, Engineering, and Medicine. The safety and quality of abortion care in the United States. Washington, DC: The National Academies Press, 2018. Available at: https://www.nap.edu/read/24950/chapter/1. Retrieved September 20, 2018.
9. Calonge BN, Gayle HD. The safety and quality of abortion services in the United States: what does the evidence indicate. Ann Intern Med 2018;168:878–80.

PEER REVIEW HISTORY

Received September 24, 2018. Received in revised form November 2, 2018. Accepted November 8, 2019. Peer reviews and author correspondence are available at http://links.lww.com/AOG/B235.

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October 19, 2021

VIA EMAIL AND FEDERAL EXPRESS
Michael J. Kennedy, J.D.
Certificate of Need and Healthcare Facility Licensure
New Jersey Department of Health
120 S. Stockton Street, 3rd Floor
Trenton, NJ 08625

Re: Waiver Request - Planned Parenthood of Northern, Central and Southern New Jersey Elizabeth Family Planning Center Examination Room
License #72038

Dear Mr. Kennedy:

On behalf of our clients, Planned Parenthood of Northern, Central, and Southern New Jersey (PPNCSNJ), please find a revised Waiver Request application form CN-28 requesting a waiver of N.J.A.C. 8:43A-19.1, which if granted, would permit PPNCSNJ to perform certain minor gynecological procedures within the designated examination rooms (Exam Rooms #1 and #2) at the licensed and existing Elizabeth Family Planning office located at 1171 Elizabeth Avenue, Elizabeth, New Jersey 07201.

Please be advised, as specified on the CN-28 Application, that Exam Room #1 has 112 square feet of space and Exam Room #2 has 129 square feet of space, exceeding the minimum required of 80 square feet for exam rooms in FGI Section 3.1-3.2.2.2(1). Toilets are immediately adjacent to these rooms.

Per your request, we are enclosing the following:

1. Full-sized signed and dated "as built" architectural plans. (Attachment A)
2. Revised and currently-dated CN-28 Application for Waiver form. (Attachment B)
3. List of Minor Gynecological Procedures to be Performed in Examination Rooms #1 and #2. (Attachment C)
4. Supporting research article form ACOG (previously submitted. (Attachment D)

If you need additional information, please feel free to contact me.

Very truly yours,

ROBERT J. FOGG

RJF/mz
Enclosure

Via Email:
cc: Fred Jacobs, Assistant Commissioner
Luisa Alexopoulos, Program Manager
Triste Brooks, Co-CEO, PPNCSNJ
Cory Neering, Co-CEO, PPNCSNJ

222288155v1

ATTACHMENT A

ATTACHMENT B

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GA LIC RA011484
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IL LIC 001.020069
MA LIC AR10286
MD LIC 12662
MI LIC 1301052189
NJ LIC AI0-12787
MN LIC 46404
NC LIC 10120
NH LIC 3501
NY LIC 024673
OH LIC A-99-12444
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PA LIC RA407927

NJ State Board Of Architects Authorization No. 161
NJ State Board Of Engineers & Land Surveyors Authorization No. 24GA28053000

Project:

MEDICAL OFFICE SPACE

1171 ELIZABETH AVENUE
ELIZABETH, NEW JERSEY

Project Number:	Scale:
PA-S-16-121	AS NOTED
Drawn By:	**Approved By:**
NB/CC	IHK

Drawing Name:

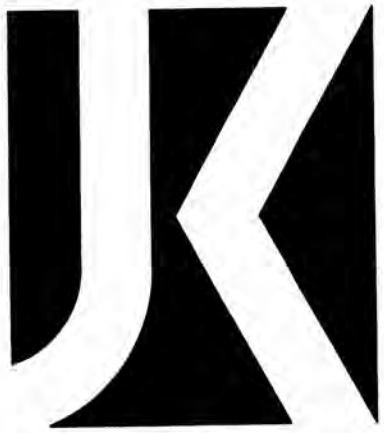
FIRST FLOOR PLAN

Drawing Number:

EX-1

Initial Date: 2-19-19

5



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ISSUE

NO.	DATE	DESCRIPTION	INT.
1	2-19-19	FOR YOUR USE	IHK
2	11-04-19	FOR YOUR USE	IHK
3	11-12-19	FOR YOUR USE	IHK
4	12-9-19	FOR YOUR USE	IHK
5	7-22-20	FOR YOUR USE	IHK
6	8-5-20	FOR YOUR USE	IHK
7	9-29-21	FOR YOUR USE	IHK

REVISION

NO.	DATE	DESCRIPTION	INT.

Casa, Wayne [DOH]

From: D' Errico, Theresa [DOH]
Sent: Tuesday, September 7, 2021 12:17 PM
To: rfogg@archerlaw.com
Subject: Waiver request Planned Parenthood of Northern, Central, and Southern New Jersey's (PPNCSNJ's) Elizabeth
Attachments: Letter to M. Kennedy re PPNCSNJ Elizabeth Exam Room Waiver 8.12.21.pdf

RE: Planned Parenthood of Northern, Central, and Southern New Jersey's (PPNCSNJ's)
1171 Elizabeth Avenue, Elizabeth, NJ 0720
License #72038
Waiver request #8374;
N.J.A.C. 8:43A-19.1
Physical Plant and Functional Requirements- Examination rooms

Dear MR. Fogg:

The Department of Health (Department) is in receipt of your correspondence and Planned Parenthood of Northern, Central, and Southern New Jersey's (PPNCSNJ's) Elizabeth facility's waiver request from N.J.A.C. 8:43A-19.1, Physical Plant and Functional Requirements, and section 2.1-3.2.1.2 of the FGI guidelines for outpatient facilities regarding exam rooms. You are requesting a waiver in order to allow PPNCSNJ's Elizabeth facility to perform certain minor gynecological procedures -colposcopy, LEEP, endometrial Bx., cryotherapy, in its examination rooms.

Please be aware that the Department does not give "blanket" waivers for licensure standards and FGI requirements. However, please provide the additional information for the Department's further review and determination for waiver.
Please submit the following:

- a waiver request that addresses each exam room requesting to be waived,
- the specific exam room, including room#, to be designated for the above minor gynecological procedures,
- the size dimensions of each designated exam room,
- a complete list of the minor gynecological procedures proposed to be provided in the requested designated exam room (s);
- a current and dated schematic drawing of the facility showing the designated exam rooms(s) that is signed and dated by the facility's Architect, is to size, scale and dimensional, and has all rooms labeled.

Thank You.

Theresa R. D'Errico, RN
Health Systems Specialist
NJ Department of Health
Certificate of Need and Licensing Program
NJ Department of Health
Certificate of Need and Healthcare Facility Licensure Program
Phone: (609) 292-6552 - **New**
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August 12, 2021

VIA EMAIL AND FEDERAL EXPRESS
Michael J. Kennedy, J.D.
Certificate of Need and Healthcare Facility Licensure
New Jersey Department of Health
120 S. Stockton Street, 3rd Floor
Trenton, NJ 08625

Re: Waiver Request - Planned Parenthood of Northern, Central and Southern New Jersey Elizabeth Family Planning Center Examination Room
License #72038

Dear Mr. Kennedy:

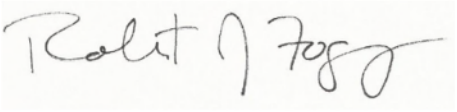
On behalf of our clients, Planned Parenthood of Northern, Central, and Southern New Jersey (PPNCSNJ), please find a completed Waiver Request application form CN-28 requesting a waiver of N.J.A.C. 8:43A-19.1, which if granted, would permit PPNCSNJ to perform certain minor gynecological procedures within the designated examination room at the licensed and existing Elizabeth Family Planning office located at 1171 Elizabeth Avenue, Elizabeth, New Jersey 07201. These procedures include the following:

1. Colposcopy
2. Loop Electrosurgical Excision Procedure (LEEP)
3. Endometrial Biopsy
4. Cryotherapy

These procedures have historically been performed safely in examination rooms to our knowledge throughout family planning centers in the State of New Jersey. At PPNCSNJ, these services are largely provided to underserved patients without charge. These are also routinely performed in private practice OB/GYN practices throughout the state without incident. The regulatory basis for the Department's interpretation is not clearly set forth in N.J.A.C. 8:43A nor is it explicitly outlined in the FGI Standards for Design and Construction of Outpatient Facilities. However, without conceding the existence of such a standard, we are submitting this waiver request for your office's review and approval, and appreciate your willingness to consider such a waiver.

If you need additional information, please feel free to contact me.

Very truly yours,



ROBERT J. FOGG

RJF/mz
Enclosure

Via Email:
cc: Fred Jacobs, Assistant Commissioner
Luisa Alexopoulos, Program Manager
Triste Brooks, Co-CEO, PPNCSNJ
Cory Neering, Co-CEO, PPNCSNJ

221802890v2

New Jersey Department of Health
Office of Certificate of Need and Healthcare Facility Licensure
P.O. Box 358
Trenton, NJ 08625-0358

APPLICATION FOR WAIVER

(Requests for more than one waiver may not be combined. An Application for Waiver form must be completed for each waiver requested).

CN Ref. #	DCA Ref. #	Facility ID # (if currently licensed)
n/a	**n/a**	**72038**

Name and Address of Facility:

Planned Parenthood of Northern, Central, and Southern NJ
1171 Elizabeth Avenue
Elizabeth, NJ 07201

Name, Address and Telephone Number of Owner, Chief Executive Officer (CEO), Chief Operating Officer (COO), or Administrator of the Existing or Proposed Facility:

Triste Brooks and Cory Neering, Co-CEO's
PPNCSNJ
196 Speedwell Avenue
Morristown NJ 07960
973-539-9580 ext 151

Name, Address and Telephone Number of Architect:

n/a

The owner, CEO, COO or Administrator of the existing or proposed health care facility hereby applies for a waiver to the following regulation (identify regulation by name, code citation (if applicable) and date (if applicable):

N.J.A.C. 8:43A-19.1 Physical Plant and Functional Requirements.
(a) New buildings and alterations and additions to existing buildings for freestanding ambulatory care facilities shall conform with the New Jersey Construction Code, NJAC 5:23, and the "construction guidelines".

APPLICATION FOR WAIVER (continued)

A. Provide the following information for each rule or part of rule for which a waiver is being requested. Attach additional sheets as necessary.

1. Restate rule or part of rule for which a waiver is being requested and identify the specific rule citation.

PPNCSNJ seeks a waiver from the Department's interpretation that the FGI Guidelines for Design and Construction of Outpatient Facilities at standard 2.1-3.2.1.2 do not permit PPNCSNJ to perform certain basic gynecological procedures, such as colcoscopies and LEEP's, in an Examination Room.

2. Describe the reasons for requesting a waiver, including a statement of the type and degree of hardship that would result upon compliance.

PPNCSNJ requests a waiver of this interpretation of the FGI standards as compliance will pose a hardship and minimize access to basic women's health services. Restricting and scheduling all colposcopies, LEEP's, and endometrial biopsies in the single Procedure Room at the Elizabeth facility will reduce PPNCSNJ's capacity to schedule and provide these services. This will minimize access by underserved populations to these essential women's health services that are within the scope of a Family Planning agency.

3. Describe an alternative proposal to ensure patient safety.

PPNCSNJ will continue to safely meet all applicable clinical standards for providing the above GYN procedures in an Examination Room. PPNCSNJ clinicians will utilize a Procedure Room for these cases whenever such GYN procedures involve invasive incisions into normally sterile body cavities requiring higher environmental controls, or involving additional instrumentation and equipment requiring the larger size of a procedure room.

4. Is documentation attached to support the waiver request?

☐No ☒Yes (Identify):

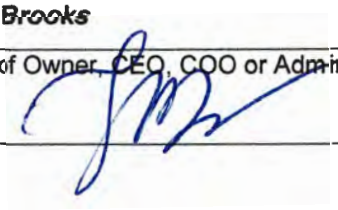
ACOG research article: "Consensus Guidelines for Facilities Performing Outpatient Procedures" concluding that increasing the size of examination rooms beyond those in effect for general medical offices is not justified for facility-based gynecological procedures and related procedures.

B. Is the project currently under review by the Department of Community Affairs, Health Care Plan Review?

☒No ☐Yes (Identify DCA Reviewer)

C. Is the request for a waiver based on plan review comments by the Department of Community Affairs.

☒No ☐Yes (Attach Comments)

Name of Owner, CEO, COO or Administrator	Title
Triste Brooks	**CEO**
Signature of Owner, CEO, COO or Administrator	Date
	8/11/21

Consensus Guidelines for Facilities Performing Outpatient Procedures

Evidence Over Ideology

Barbara S. Levy, MD, Debra L. Ness, MS, and Steven E. Weinberger, MD

In policy and law, regulation of abortion is frequently treated differently from other health services. The safety of abortion is similar to that of other types of office- and clinic-based procedures, and facility requirements should be based on assuring high-quality, safe performance of all such procedures. False concerns for patient safety are being used as a justification for promoting regulations that specifically target abortion. The Project on Facility Guidelines for the Safe Performance of Primary Care and Gynecology Procedures in Offices and Clinics was undertaken by clinicians, consumers, and representatives from accrediting bodies to review the available evidence and guidelines that inform safe delivery of outpatient care. Our overall objective was to develop evidence-informed consensus guidelines to promote health care quality, safety, and accessibility. Our consensus determined that requiring facilities performing office-based procedures, including abortion, to meet standards beyond those currently in effect for all general medical offices and clinics is unjustified based on an analysis of available evidence. No safety concerns were identified.

(Obstet Gynecol 2019;133:255–60)
DOI: 10.1097/AOG.0000000000003058

From the American College of Obstetricians and Gynecologists and National Partnership for Women & Families, Washington, DC; and the American College of Physicians, Philadelphia, Pennsylvania.

Supported by staff at the American College of Obstetricians and Gynecologists, the Advancing New Standards in Reproductive Health (ANSIRH) program at the University of California, San Francisco, and the National Partnership for Women & Families. Support for the costs of the Project was provided by these organizations, as well as by an anonymous U.S.-based, 501(c)(3), charitable foundation. The foundation had no influence on, or involvement in, the Project process, meeting, document creation, or other activities. In-kind support for the Project was provided by the members of the Procedures Working Group and the organizations represented on the planning committee.

The authors thank Bonnie Scott Jones and Molly Battistelli, of Advancing New Standards in Reproductive Health (ANSIRH), University of California, San Francisco, as well as Sarah Horvath, MD, and Jennie Shaw, MPH, American College of Obstetricians and Gynecologists, for their assistance in the drafting process.

The Procedures Working Group list is in Appendix 1, available online at http://links.lww.com/AOG/B234.

Each author has confirmed compliance with the journal's requirements for authorship.

Corresponding author: Barbara S. Levy, MD, Vice President, Health Policy, American College of Obstetricians and Gynecologists, 409 12th Street SW, Washington, DC 20024-2188; email: blevy@acog.org.

Financial Disclosure
The authors did not report any potential conflicts of interest.

ISSN: 0029-7844/19

Government has a legitimate role in protecting the public by establishing standards and requirements for health care provider licensure. However, many proposed laws and regulations at both the state and national levels lack scientific evidence to support any safety concerns defining a need or benefit to patients resulting from those requirements.[1] Some of these laws apply broadly to outpatient settings in which surgery, procedures, or certain levels of sedation are offered; others apply specifically to abortion. They target clinics and facilities that provide medication-induced as well as procedural abortion services. Currently, 16 states have requirements for licensing abortion clinics similar to those for ambulatory surgical centers, whereas 19 require specific dimensions for procedure rooms and corridors.[2] Additionally, 21 states require abortion clinic providers to maintain a relationship with a local hospital.[2] Laws of this nature can have a profound effect on access to abortion, as exhibited by the decline in Texas from 46 clinics in 2011 to 28 clinics in 2014 after passage of onerous facility restrictions.[3] By 2014, 90% of U. S. counties, in which 39% of reproductive age women live, had no clinics providing abortion care.[3]

Procedures are a critical part of both primary care and gynecologic care. Offering procedures in office and clinic settings has the potential to significantly improve patient care, access, affordability, and experience. The American College of Obstetricians and Gynecologists defines a procedure as "a short interventional technique that includes the following general categories:[4]

- Nonincisional diagnostic or therapeutic intervention through a natural body cavity or orifice
- Superficial incisional or excisional diagnostic or therapeutic intervention that does not involve repair or significantly alter morphology
- Device placement into a natural cavity
- Subcutaneous implant
- Injections

The American College of Obstetricians and Gynecologists states that the classification of an intervention as a "procedure" should be based on the nature of the intervention itself and not on the location at which the procedure is performed.

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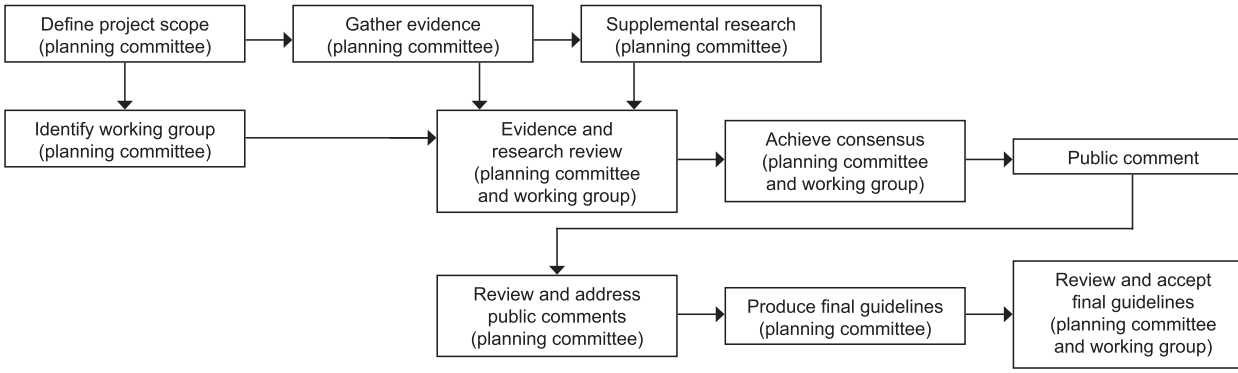

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Box 1. Facility Factor

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  - Facility emergencies
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1. First, the planning committee enlisted a researcher to review the literature for information about how facility laws affect access to health care services in offices and clinics. The researcher found limited published research on the topic, the bulk of which addressed three policy areas (the Mammography Quality Standards Act, the Clinical Laboratory Improvement Amendments, and state-level facility requirements governing the provision of abortion). The limited evidence available suggests that the effect of new facility regulation on patients' access to care depends largely on whether such regulation is attuned to patient and facility needs and includes measures to support facilities as they seek to come into compliance.
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The Project produced consensus guidelines (Box 2) that will further evidence-informed facility practices and policies for primary care and gynecology procedures, including abortion. Feedback on the draft guidelines was solicited from stakeholders and members of the public via a public comment process from April 17, 2018 to May 13, 2018. The draft was posted on an interactive, public website that allowed for submission of comments, proposed edits, and additional evidence. Announcements of the public comment period were sent to health professional and health care organizations according to outreach processes commonly used in the development of clinical guidelines. The feedback provided during the public comment process was thoroughly reviewed and considered by the planning committee. Overall, the comments were supportive and indicated the guidelines were appropriate as written. In some cases, the planning committee made minor revisions or clarifications to the draft guidelines as appropriate and justified by the evidence. The Procedures Working Group reviewed the revised guidelines, gave feedback as necessary, and came to consensus on the content of the final guidelines.

Participants found no evidence of any patient safety or quality-of-care problems related to the examined facility factors in offices or clinics that

Box 2. Facility Guidelines

Facilities' policies, procedures, and supplies should be suited to the nature of the practice and procedures performed. In some facilities, appropriate policies, procedures, and supplies will be minimal. Solo or small practices that perform only occasional, limited procedures should assess which of the guidelines are appropriate to the practice given the procedures performed at the site.

Emergency Preparedness

- Facilities should establish written policies and procedures for managing facility emergencies (eg, natural disaster, fire) and patient emergencies (eg, vasovagal reaction, hemorrhage) and should conduct periodic drills and staff trainings on those policies and procedures. A formal transfer agreement with a hospital is not required because transfers are rare and hospitals are required to accept patients with emergent needs. Good communications in the event of a transfer and working relationships with facilities that may receive or refer patients are encouraged.
- Facilities should have a staff person trained in basic life support onsite when procedures are performed and have a person other than the clinician performing the procedure onsite to provide assistance, call for additional assistance, or transport to a hospital in an emergency.
- Facilities should maintain adequate supplies for basic life support and medications and equipment needed to treat emergencies that may occur with the procedures performed.
- Facilities should provide basic emergency lighting (eg, battery backup lighting, flashlights).
- Facilities should keep doorways and hallways free of obstructions that could impede exit by patients and staff or ingress by emergency personnel. Where the types and risks of procedures performed at the facility create a reasonable likelihood that patient transfer by stretcher may be needed, doorways and hallways in the path of egress should be sufficiently wide to permit passage by stretcher (note that this term includes chair stretchers, which can be maneuvered through typical office doorways and hallways).
- Facilities should provide wayfinding signage that is understandable to the patient population served.

Biological Material Handling

- Facilities should establish written policies and procedures for properly labeling, handling, and storing biological specimens to be sent to pathology or other laboratory. The decision of whether to send specimens for pathology evaluation is made by the clinician or on the basis of facility policies.
- Facilities should establish written policies and procedures for handling, storing, and disposing of hazardous materials in a manner that minimizes the risk of exposure and for reducing the risk of harm to individuals involved, should exposure occur. Tissue not sent to pathology should be disposed of in the same manner as other biological materials. Tissue used in research or commercial endeavors is subject to separate requirements not addressed in this document.

Box 2. Facility Guidelines

Biological Material Handling (*continued*)

- Facilities should conduct periodic staff training on the policies and procedures described.

Physical Plant Specifications*

- Facilities should consider patient privacy, confidentiality, and comfort in the design and flow of the facility.
- Facilities should perform procedures in examination rooms or procedure rooms adequate to accommodate the equipment and personnel involved in the procedure. Typical examination rooms are an adequate size for most procedures; a room larger than needed to accommodate the equipment and personnel involved in the procedure is neither necessary nor desirable.
- Facilities should have patients recover in the room in which the procedure was performed or in a separate recovery room or area. A separate recovery room is not required. Some procedures require no recovery time.
- Facilities should provide separate storage for clean and dirty supplies.
- If instruments are sterilized onsite, facilities should provide separate marked areas for soiled and clean instrument processing. Separate rooms for those functions are not required. Offsite sterilization services may also be used.
- Facilities should provide a source of emergency power for equipment if any of the procedures performed in the facility are ones in which a power loss during the procedure would threaten patient safety.
- Facilities should have onsite, and maintain in good condition, the equipment needed for the procedures performed.
- Facilities should use adequate heating, ventilation, and cooling systems. Systems typical for offices are adequate in this context; no special heating, ventilation, or cooling systems are needed.
- Facilities that store specimens or medications requiring refrigeration should provide separate refrigerated storage for each.

Facility Accreditation and Licensing

- Procedures should be provided in facilities that meet current accepted practices. Such accepted practices do not require facility accreditation or facility licensing.

Clinician Qualifications Beyond Licensing

- Facilities should ensure that clinical staff are trained in the procedures performed, equipment used in the facility, basic life support, cultural sensitivity, and any requirements governing the facility with regard to accommodations to facilitate safe and appropriate access to health services for individuals with disabilities or other conditions, including limited English proficiency. Although some facilities will have no need for nursing staff, facilities should ensure that any clinical duties requiring nursing care are staffed appropriately.

Box 2. Facility Guidelines

Clinical Qualifications Beyond Licensing (*continued*)

- Facilities should designate a clinician responsible for ensuring that clinicians who perform procedures at the facility have established competence in those procedures. Such competence may be established through any of a variety of training, education, and assessment activities (which may be specified by the facility, a professional organization, or specialty). Neither board certification nor hospital privileges are required.

Other Policies and Procedures

- Facilities should establish written policies and procedures for infection control, conduct periodic staff training on those policies and procedures, and implement a plan to monitor compliance.
- Facilities that perform procedures on more than an occasional basis should establish a written quality improvement plan that includes recording and reviewing available facility data on select adverse outcomes related to procedures performed and ways to act on information gained.
- Facilities should establish a written policy and schedule for checking equipment functioning.
- Facilities should establish a written policy and schedule for managing medication inventory.

*We have included some physical plant–related matters in the guidelines for emergency preparedness.

provide primary care and gynecology procedures. Given the available evidence, the Procedures Working Group concluded that there is insufficient research to find that particular facility factors have either a positive or negative effect on patient safety or experience (very little research has been conducted in these areas, and the findings from that limited research are not definitive). The Procedures Working Group also noted that research suggests the possibility that some facility requirements may result in decreased service availability.[5] These findings mirror those of the National Academies of Sciences, Engineering, and Medicine, which recently published their report, "The Safety and Quality of Abortion Care in the United States." They, too, conducted a comprehensive literature review. Using a quality lens and the six dimensions of care quality–safety, effectiveness, efficiency, timeliness, equity, and patient-centered care–the authors found no evidence that regulations targeted at abortion care improved safety. They did find that other aspects of quality care delivery were negatively affected by those regulations–specifically, access to care, timeliness, and the availability of local, qualified providers.[8,9]

CONCLUSIONS

Requiring facilities that perform office-based procedures, including abortion, to meet standards beyond those currently in effect for all general medical offices and clinics is unjustified based on this thorough review and analysis of available evidence; safety concerns were not identified in any area of study.

The consensus guidelines developed by committee experts and stakeholders through systematic review of the literature, provide an evidence-informed basis for evaluating legislation and regulations that use patient safety as a justification for restrictive and ideologically driven policies. This research provides the evidence base to conclude that additional regulation for outpatient procedures, including abortion, has no documented necessity. Targeting specific procedures based on ideology rather than evidence sets a dangerous precedent for the regulation of medicine. It is essential for all health care providers and advocates to evaluate new and proposed facility requirements according to available evidence as outlined in this document. When such regulations are deemed unnecessary, it is incumbent on these same experts to oppose them. Enacting superfluous facility requirements is politics, not public safety.

REFERENCES

1. Weinberger SE, Lawrence HC, III, Henley DE, Alden ER, Hoyt DB. Legislative interference with the patient-physician relationship. N Engl J Med 2012;367:1557–9.
2. Guttmacher Institute. Targeted regulation of abortion providers. Available at: https://www.guttmacher.org/state-policy/explore/targeted-regulation-abortion-providers. Retrieved September 20, 2018.
3. Guttmacher Institute. State facts about abortion. Texas. Available at: https://www.guttmacher.org/fact-sheet/state-facts-about-abortion-texas. Retrieved September 20, 2018.
4. American College of Obstetricians and Gynecologists. Definition of "procedures" related to obstetrics and gynecology: position statement. Available at: https://www.acog.org/Clinical-Guidance-and-Publications/Position-Statements/Definition-of-Procedures-Related-to-Ob-Gyn. Retrieved September 20, 2018.
5. Berglas NF, Battistelli MF, Nicholson WK, Sobota M, Urman RD, Roberts SCM. The effect of facility characteristics on patient safety, patient experience, and service availability for procedures in non-hospital-affiliated outpatient settings: a systematic review. PLoS One 2018;13:e0190975.
6. Brouwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al. AGREE II: advancing guideline development, reporting and evaluation in health care. Can Med Assoc J 2010;182:E839–42.
7. Spruce L, Van Wicklin SA, Hicks RW, Conner R, Dunn D. Introducing AORN's new model for evidence rating. AORN J 2014;99:243–55.
8. National Academies of Sciences, Engineering, and Medicine. The safety and quality of abortion care in the United States. Washington, DC: The National Academies Press, 2018. Available at: https://www.nap.edu/read/24950/chapter/1. Retrieved September 20, 2018.
9. Calonge BN, Gayle HD. The safety and quality of abortion services in the United States: what does the evidence indicate. Ann Intern Med 2018;168:878–80.

PEER REVIEW HISTORY

Received September 24, 2018. Received in revised form November 2, 2018. Accepted November 8, 2019. Peer reviews and author correspondence are available at http://links.lww.com/AOG/B235.

New Jersey Department of Health
Office of Certificate of Need and Healthcare Facility Licensure
P.O. Box 358
Trenton, NJ 08625-0358

W-8374 TD

APPLICATION FOR WAIVER

(Requests for more than one waiver may not be combined. An Application for Waiver form must be completed for each waiver requested).

CN Ref. #	DCA Ref. #	Facility ID # (if currently licensed)
n/a	n/a	72038

Name and Address of Facility:

Planned Parenthood of Northern, Central, and Southern NJ
1171 Elizabeth Avenue
Elizabeth, NJ 07201

Name, Address and Telephone Number of Owner, Chief Executive Officer (CEO), Chief Operating Officer (COO), or Administrator of the Existing or Proposed Facility:

Triste Brooks and Cory Neering, Co-CEO's
PPNCSNJ
196 Speedwell Avenue
Morristown NJ 07960
973-539-9580 ext 151

Name, Address and Telephone Number of Architect:

n/a

The owner, CEO, COO or Administrator of the existing or proposed health care facility hereby applies for a waiver to the following regulation (identify regulation by name, code citation (if applicable) and date (if applicable):

N.J.A.C. 8:43A-19.1 Physical Plant and Functional Requirements.
(a) New buildings and alterations and additions to existing buildings for freestanding ambulatory care facilities shall conform with the New Jersey Construction Code, NJAC 5:23, and the "construction guidelines".

APPLICATION FOR WAIVER (continued)

A. Provide the following information for each rule or part of rule for which a waiver is being requested. Attach additional sheets as necessary.

1. Restate rule or part of rule for which a waiver is being requested and identify the specific rule citation.

PPNCSNJ seeks a waiver from the Department's interpretation that the FGI Guidelines for Design and Construction of Outpatient Facilities at standard 2.1-3.2.1.2 do not permit PPNCSNJ to perform certain basic gynecological procedures, such as colcoscopies and LEEP's, in an Examination Room.

2. Describe the reasons for requesting a waiver, including a statement of the type and degree of hardship that would result upon compliance.

PPNCSNJ requests a waiver of this interpretation of the FGI standards as compliance will pose a hardship and minimize access to basic women's health services. Restricting and scheduling all colposcopies, LEEP's, and endometrial biopsies in the single Procedure Room at the Elizabeth facility will reduce PPNCSNJ's capacity to schedule and provide these services. This will minimize access by underserved populations to these essential women's health services that are within the scope of a Family Planning agency.

3. Describe an alternative proposal to ensure patient safety.

PPNCSNJ will continue to safely meet all applicable clinical standards for providing the above GYN procedures in an Examination Room. PPNCSNJ clinicians will utilize a Procedure Room for these cases whenever such GYN procedures involve invasive incisions into normally sterile body cavities requiring higher environmental controls, or involving additional instrumentation and equipment requiring the larger size of a procedure room.

4. Is documentation attached to support the waiver request?

☐No ☒Yes (Identify):

ACOG research article: "Consensus Guidelines for Facilities Performing Outpatient Procedures" concluding that increasing the size of examination rooms beyond those in effect for general medical offices is not justified for facility-based gynecological procedures and related procedures.

B. Is the project currently under review by the Department of Community Affairs, Health Care Plan Review?

☒No ☐Yes (Identify DCA Reviewer)

C. Is the request for a waiver based on plan review comments by the Department of Community Affairs.

☒No ☐Yes (Attach Comments)

Name of Owner, CEO, COO or Administrator	Title
Triste Brooks	**CEO**
Signature of Owner, CEO, COO or Administrator	Date
	8/11/21

Consensus Guidelines for Facilities Performing Outpatient Procedures

Evidence Over Ideology

Barbara S. Levy, MD, Debra L. Ness, MS, and Steven E. Weinberger, MD

In policy and law, regulation of abortion is frequently treated differently from other health services. The safety of abortion is similar to that of other types of office- and clinic-based procedures, and facility requirements should be based on assuring high-quality, safe performance of all such procedures. False concerns for patient safety are being used as a justification for promoting regulations that specifically target abortion. The Project on Facility Guidelines for the Safe Performance of Primary Care and Gynecology Procedures in Offices and Clinics was undertaken by clinicians, consumers, and representatives from accrediting bodies to review the available evidence and guidelines that inform safe delivery of outpatient care. Our overall objective was to develop evidence-informed consensus guidelines to promote health care quality, safety, and accessibility. Our consensus determined that requiring facilities performing office-based procedures, including abortion, to meet standards beyond those currently in effect for all general medical offices and clinics is unjustified based on an analysis of available evidence. No safety concerns were identified.

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Government has a legitimate role in protecting the public by establishing standards and requirements for health care provider licensure. However, many proposed laws and regulations at both the state and national levels lack scientific evidence to support any safety concerns defining a need or benefit to patients resulting from those requirements.[1] Some of these laws apply broadly to outpatient settings in which surgery, procedures, or certain levels of sedation are offered; others apply specifically to abortion. They target clinics and facilities that provide medication-induced as well as procedural abortion services. Currently, 16 states have requirements for licensing abortion clinics similar to those for ambulatory surgical centers, whereas 19 require specific dimensions for procedure rooms and corridors.[2] Additionally, 21 states require abortion clinic providers to maintain a relationship with a local hospital.[2] Laws of this nature can have a profound effect on access to abortion, as exhibited by the decline in Texas from 46 clinics in 2011 to 28 clinics in 2014 after passage of onerous facility restrictions.[3] By 2014, 90% of U. S. counties, in which 39% of reproductive age women live, had no clinics providing abortion care.[3]

From the American College of Obstetricians and Gynecologists and National Partnership for Women & Families, Washington, DC; and the American College of Physicians, Philadelphia, Pennsylvania.

Supported by staff at the American College of Obstetricians and Gynecologists, the Advancing New Standards in Reproductive Health (ANSIRH) program at the University of California, San Francisco, and the National Partnership for Women & Families. Support for the costs of the Project was provided by these organizations, as well as by an anonymous U.S.-based, 501(c)(3), charitable foundation. The foundation had no influence on, or involvement in, the Project process, meeting, document creation, or other activities. In-kind support for the Project was provided by the members of the Procedures Working Group and the organizations represented on the planning committee.

The authors thank Bonnie Scott Jones and Molly Battistelli, of Advancing New Standards in Reproductive Health (ANSIRH), University of California, San Francisco, as well as Sarah Horvath, MD, and Jennie Shaw, MPH, American College of Obstetricians and Gynecologists, for their assistance in the drafting process.

The Procedures Working Group list is in Appendix 1, available online at http://links.lww.com/AOG/B234.

Each author has confirmed compliance with the journal's requirements for authorship.

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Financial Disclosure
The authors did not report any potential conflicts of interest.

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Procedures are a critical part of both primary care and gynecologic care. Offering procedures in office and clinic settings has the potential to significantly improve patient care, access, affordability, and experience. The American College of Obstetricians and Gynecologists defines a procedure as "a short interventional technique that includes the following general categories:[4]

- Nonincisional diagnostic or therapeutic intervention through a natural body cavity or orifice
- Superficial incisional or excisional diagnostic or therapeutic intervention that does not involve repair or significantly alter morphology
- Device placement into a natural cavity
- Subcutaneous implant
- Injections

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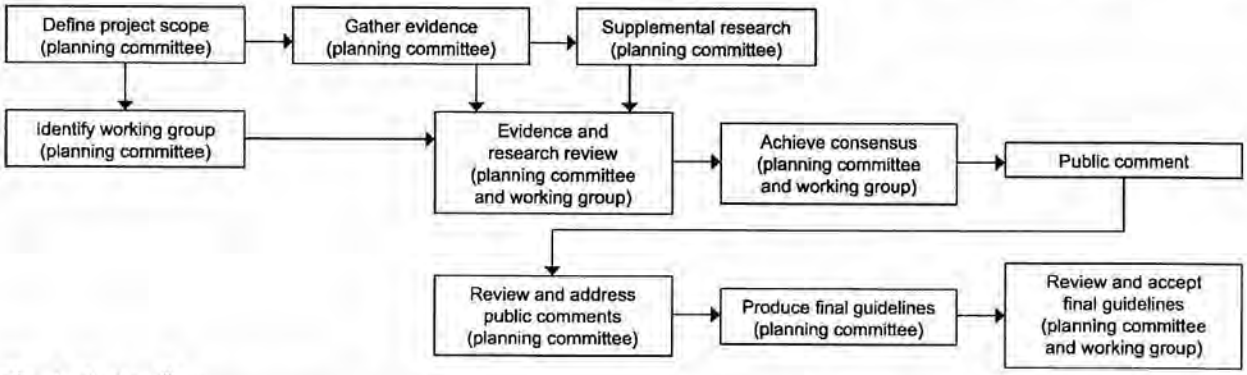

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3. Third, to determine whether any relevant public health or patient safety issues related to facility factors had been documented, research was undertaken to examine press releases, published guidance, and opinions from state medical boards and selected health professional organizations. This research found no documentation of any public health or patient safety issues related to facility factors in offices or clinics providing primary care or gynecology procedures.

At an in-person meeting, participants analyzed the available evidence, shared current accepted practices, and discussed whether any evidence of potential harms exists in six areas: emergency preparedness, biological material handling, physical plant specifications, facility accreditation and licensing, clinician qualifications beyond licensing, and other policies and procedures. Researchers examined outpatient accrediting body requirements and state facility laws for office and clinic settings to ensure inclusion. An iterative process then was used to reach consensus among Procedures Working Group members about current accepted practices, areas of possible concern, and the potential need for changes to current accepted practices in each area.

The Project produced consensus guidelines (Box 2) that will further evidence-informed facility practices and policies for primary care and gynecology procedures, including abortion. Feedback on the draft guidelines was solicited from stakeholders and members of the public via a public comment process from April 17, 2018 to May 13, 2018. The draft was posted on an interactive, public website that allowed for submission of comments, proposed edits, and additional evidence. Announcements of the public comment period were sent to health professional and health care organizations according to outreach processes commonly used in the development of clinical guidelines. The feedback provided during the public comment process was thoroughly reviewed and considered by the planning committee. Overall, the comments were supportive and indicated the guidelines were appropriate as written. In some cases, the planning committee made minor revisions or clarifications to the draft guidelines as appropriate and justified by the evidence. The Procedures Working Group reviewed the revised guidelines, gave feedback as necessary, and came to consensus on the content of the final guidelines.

Participants found no evidence of any patient safety or quality-of-care problems related to the examined facility factors in offices or clinics that

Box 2. Facility Guidelines

Facilities' policies, procedures, and supplies should be suited to the nature of the practice and procedures performed. In some facilities, appropriate policies, procedures, and supplies will be minimal. Solo or small practices that perform only occasional, limited procedures should assess which of the guidelines are appropriate to the practice given the procedures performed at the site.

Emergency Preparedness

- Facilities should establish written policies and procedures for managing facility emergencies (eg, natural disaster, fire) and patient emergencies (eg, vasovagal reaction, hemorrhage) and should conduct periodic drills and staff trainings on those policies and procedures. A formal transfer agreement with a hospital is not required because transfers are rare and hospitals are required to accept patients with emergent needs. Good communications in the event of a transfer and working relationships with facilities that may receive or refer patients are encouraged.
- Facilities should have a staff person trained in basic life support onsite when procedures are performed and have a person other than the clinician performing the procedure onsite to provide assistance, call for additional assistance, or transport to a hospital in an emergency.
- Facilities should maintain adequate supplies for basic life support and medications and equipment needed to treat emergencies that may occur with the procedures performed.
- Facilities should provide basic emergency lighting (eg, battery backup lighting, flashlights).
- Facilities should keep doorways and hallways free of obstructions that could impede exit by patients and staff or ingress by emergency personnel. Where the types and risks of procedures performed at the facility create a reasonable likelihood that patient transfer by stretcher may be needed, doorways and hallways in the path of egress should be sufficiently wide to permit passage by stretcher (note that this term includes chair stretchers, which can be maneuvered through typical office doorways and hallways).
- Facilities should provide wayfinding signage that is understandable to the patient population served.

Biological Material Handling

- Facilities should establish written policies and procedures for properly labeling, handling, and storing biological specimens to be sent to pathology or other laboratory. The decision of whether to send specimens for pathology evaluation is made by the clinician or on the basis of facility policies.
- Facilities should establish written policies and procedures for handling, storing, and disposing of hazardous materials in a manner that minimizes the risk of exposure and for reducing the risk of harm to individuals involved, should exposure occur. Tissue not sent to pathology should be disposed of in the same manner as other biological materials. Tissue used in research or commercial endeavors is subject to separate requirements not addressed in this document.

Box 2. Facility Guidelines

Biological Material Handling *(continued)*

- Facilities should conduct periodic staff training on the policies and procedures described.

Physical Plant Specifications*

- Facilities should consider patient privacy, confidentiality, and comfort in the design and flow of the facility.
- Facilities should perform procedures in examination rooms or procedure rooms adequate to accommodate the equipment and personnel involved in the procedure. Typical examination rooms are an adequate size for most procedures; a room larger than needed to accommodate the equipment and personnel involved in the procedure is neither necessary nor desirable.
- Facilities should have patients recover in the room in which the procedure was performed or in a separate recovery room or area. A separate recovery room is not required. Some procedures require no recovery time.
- Facilities should provide separate storage for clean and dirty supplies.
- If instruments are sterilized onsite, facilities should provide separate marked areas for soiled and clean instrument processing. Separate rooms for those functions are not required. Offsite sterilization services may also be used.
- Facilities should provide a source of emergency power for equipment if any of the procedures performed in the facility are ones in which a power loss during the procedure would threaten patient safety.
- Facilities should have onsite, and maintain in good condition, the equipment needed for the procedures performed.
- Facilities should use adequate heating, ventilation, and cooling systems. Systems typical for offices are adequate in this context; no special heating, ventilation, or cooling systems are needed.
- Facilities that store specimens or medications requiring refrigeration should provide separate refrigerated storage for each.

Facility Accreditation and Licensing

- Procedures should be provided in facilities that meet current accepted practices. Such accepted practices do not require facility accreditation or facility licensing.

Clinician Qualifications Beyond Licensing

- Facilities should ensure that clinical staff are trained in the procedures performed, equipment used in the facility, basic life support, cultural sensitivity, and any requirements governing the facility with regard to accommodations to facilitate safe and appropriate access to health services for individuals with disabilities or other conditions, including limited English proficiency. Although some facilities will have no need for nursing staff, facilities should ensure that any clinical duties requiring nursing care are staffed appropriately.

Box 2. Facility Guidelines

Clinical Qualifications Beyond Licensing *(continued)*

- Facilities should designate a clinician responsible for ensuring that clinicians who perform procedures at the facility have established competence in those procedures. Such competence may be established through any of a variety of training, education, and assessment activities (which may be specified by the facility, a professional organization, or specialty). Neither board certification nor hospital privileges are required.

Other Policies and Procedures

- Facilities should establish written policies and procedures for infection control, conduct periodic staff training on those policies and procedures, and implement a plan to monitor compliance.
- Facilities that perform procedures on more than an occasional basis should establish a written quality improvement plan that includes recording and reviewing available facility data on select adverse outcomes related to procedures performed and ways to act on information gained.
- Facilities should establish a written policy and schedule for checking equipment functioning.
- Facilities should establish a written policy and schedule for managing medication inventory.

*We have included some physical plant–related matters in the guidelines for emergency preparedness.

provide primary care and gynecology procedures. Given the available evidence, the Procedures Working Group concluded that there is insufficient research to find that particular facility factors have either a positive or negative effect on patient safety or experience (very little research has been conducted in these areas, and the findings from that limited research are not definitive). The Procedures Working Group also noted that research suggests the possibility that some facility requirements may result in decreased service availability.[5] These findings mirror those of the National Academies of Sciences, Engineering, and Medicine, which recently published their report, "The Safety and Quality of Abortion Care in the United States." They, too, conducted a comprehensive literature review. Using a quality lens and the six dimensions of care quality–safety, effectiveness, efficiency, timeliness, equity, and patient-centered care–the authors found no evidence that regulations targeted at abortion care improved safety. They did find that other aspects of quality care delivery were negatively affected by those regulations–specifically, access to care, timeliness, and the availability of local, qualified providers.[8,9]

CONCLUSIONS

Requiring facilities that perform office-based procedures, including abortion, to meet standards beyond those currently in effect for all general medical offices and clinics is unjustified based on this thorough review and analysis of available evidence; safety concerns were not identified in any area of study.

The consensus guidelines developed by committee experts and stakeholders through systematic review of the literature, provide an evidence-informed basis for evaluating legislation and regulations that use patient safety as a justification for restrictive and ideologically driven policies. This research provides the evidence base to conclude that additional regulation for outpatient procedures, including abortion, has no documented necessity. Targeting specific procedures based on ideology rather than evidence sets a dangerous precedent for the regulation of medicine. It is essential for all health care providers and advocates to evaluate new and proposed facility requirements according to available evidence as outlined in this document. When such regulations are deemed unnecessary, it is incumbent on these same experts to oppose them. Enacting superfluous facility requirements is politics, not public safety.

REFERENCES

1. Weinberger SE, Lawrence HC, III, Henley DE, Alden ER, Hoyt DB. Legislative interference with the patient-physician relationship. N Engl J Med 2012;367:1557–9.
2. Guttmacher Institute. Targeted regulation of abortion providers. Available at: https://www.guttmacher.org/state-policy/explore/targeted-regulation-abortion-providers. Retrieved September 20, 2018.
3. Guttmacher Institute. State facts about abortion. Texas. Available at: https://www.guttmacher.org/fact-sheet/state-facts-about-abortion-texas. Retrieved September 20, 2018.
4. American College of Obstetricians and Gynecologists. Definition of "procedures" related to obstetrics and gynecology: position statement. Available at: https://www.acog.org/Clinical-Guidance-and-Publications/Position-Statements/Definition-of-Procedures-Related-to-Ob-Gyn. Retrieved September 20, 2018.
5. Berglas NF, Battistelli MF, Nicholson WK, Sobota M, Urman RD, Roberts SCM. The effect of facility characteristics on patient safety, patient experience, and service availability for procedures in non-hospital-affiliated outpatient settings: a systematic review. PLoS One 2018;13:e0190975.
6. Bronwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al. AGREE II: advancing guideline development, reporting and evaluation in health care. Can Med Assoc J 2010;182:E839–42.
7. Spruce L, Van Wicklin SA, Hicks RW, Conner R, Dunn D. Introducing AORN's new model for evidence rating. AORN J 2014;99:243–55.
8. National Academies of Sciences, Engineering, and Medicine. The safety and quality of abortion care in the United States. Washington, DC: The National Academies Press, 2018. Available at: https://www.nap.edu/read/24950/chapter/1. Retrieved September 20, 2018.
9. Calonge BN, Gayle HD. The safety and quality of abortion services in the United States: what does the evidence indicate. Ann Intern Med 2018;168:878–80.

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