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Planned Parenthood Affiliates of California

Beth Parker, Chief Legal Counsel
Planned Parenthood Affiliates of California
555 Capitol Mall, Suite 510
Sacramento, CA 95814

April 5, 2013

California Building Standards Commission
2525 Natomas Park Drive, Suite 130
Sacramento, CA 95833
*Attention: Jim McGowan, Executive Director*

**Participation Comments for the Notice Dated February 20, 2013**

Dear Mr. McGowan:

Enclosed please find Participation Comments for the Notice dated February 20, 2013, submitted on behalf of Planned Parenthood Affiliates of California in connection with OSHPD 3SE clinics.

Sincerely,

Beth H. Parker
Chief Legal Counsel

STATE OF CALIFORNIA
STATE AND CONSUMER SERVICES AGENCY
CALIFORNIA BUILDING STANDARDS COMMISSION
2525 NATOMAS PARK DR., SUITE 130
SACRAMENTO, CA 95833
(916) 263-0916 Phone
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Email: cbsc@dgs.ca.gov

Office Use Item No. _____

**PARTICIPATION COMMENTS FOR THE NOTICE DATED FEBRUARY 20, 2013.**
**Written comments are to be sent to the above address.**

**WRITTEN COMMENT DEADLINE: APRIL 5, 2013**

Date: April 5, 2013

From: Beth H. Parker
Name (Print or type) (Signature)

-- Chief Legal Counsel, Planned Parenthood Affiliates of California
Agency, jurisdiction, chapter, company, association, individual, etc.

555 Capitol Mall, Suite 510 Sacramento California 95814-4581
Street City State Zip

I/We (do) agree with:

[X ] The Agency proposed modifications As Submitted on Section No. 217.0(1)

and request that this section or reference provision be recommended:

[ ] Approved [ ] Disapproved [ ] Held for Further Study [X] Approved as Amended

**Suggested Revisions to the Text of the Regulations:**

Add "and § 1226.7 (i.e. clinics providing abortion services where treatment rooms are sized as examination rooms, as described in § 1226.7.1)" to 217.0(1) after "primary care clinics providing services limited to those listed in California Building Code § 1226.6 (i.e. clinics without treatment rooms and that perform procedures limited to those that may be performed in exam rooms as defined in California Building Code § 1224.3)."

**Reason:**

The exclusion of primary care clinics providing abortion services where treatment rooms are sized as examination rooms (§ 1226.7) from the OSHPD 3SE exemption is contrary to the public interest and unconstitutional. The exclusion is not justified by legitimate health and safety concerns. See attached analysis.

**Proposed Regulation 217.0: OSHPD 3SE excludes § 1226.7: "Primary Care Clinics that do not provide abortion services."**

OSHPD is proposing to create a subcategory of OSHPD 3 clinics that are exempt from certain existing mechanical and plumbing code requirements. The stated purpose is to align OSHPD 3SE clinic requirements with national standards. This will reduce costs to clinics without compromising patient safety. This will facilitate the construction of new primary care clinics to accommodate the increased number of patients providers will see as a result of health care reform.

OSHPD, however, has refused to include within the OSHPD 3SE exemption primary care clinics that perform abortion services where the treatment room is sized as an examination room (sec. 1226.7). This refusal is both medically unjustified and unconstitutional. Planned Parenthood Affiliates of California, therefore, recommends that the Building Standards Commission amend the proposed OSHPD 3SE exemption to include § 1226.7 (i.e. clinics providing abortion services where treatment rooms are sized as examination rooms, as described in § 1226.7.1). This will create parity between primary care clinics that provide early abortion services and those that do not. This will enable the eight California Planned Parenthood affiliates, which currently serve one million patients in 100 health centers, as well as other providers, to build new facilities to accommodate patients entering the health care system as a result of the Affordable Care Act.

The inclusion of primary care clinics that offer abortion services in the OSHPD 3SE exemption is consistent with the goals that OSHPD is trying to achieve. The elimination of the distinction would be consistent with national standards. It would also help reduce the cost of construction of community clinics that serve low income populations, thereby increasing access to much needed health care services. If primary care clinics that offer medication or aspiration abortions are excluded from the exemption, it will increase the cost of and decrease access to abortion. By our calculation, the additional plumbing and mechanical requirements will increase costs by approximately 18%. If, for example, it costs $2 million to renovate a clinic for primary care, it would cost approximately $317,000 to satisfy the additional but wholly unnecessary mechanical and plumbing code requirements needed to provide abortion care.

**There is No Medical Justification for Excluding Primary Care Clinics that Provide Abortion Services from the Exemption**

There is no medical reason to differentiate between the services set forth in § 1226.6, which are included in the OSHPD 3SE exemption, and medication and aspiration abortion services referred to in § 1226.7, which are not. This section was included in the code decades ago, shortly after abortion became legal, when abortions were performed in hospitals using very different procedures than are used today. In the intervening years, abortion has become a very routine, outpatient and low-risk procedure. The differentiation between primary care clinics that offer early abortion services and those that do not is anachronistic and provides no basis for requiring heightened building standards.

Women terminate first trimester pregnancies either by taking pills ("medication abortion") or by a simple aspiration procedure lasting under five minutes that does not involve cutting or suturing tissue

("aspiration abortion"). When performed by trained clinicians, early abortions are safe and common, posing less risk of infection than many other procedures performed in primary care clinics eligible for the OSHPD 3SE classification. For medication abortions, there is no difference between taking a pill for a cold or taking one to induce an abortion. For aspiration abortions, the risk of infection is no different than the risk for insertion of an intrauterine device or for an endometrial biopsy. Yet, under OSHPD's proposal, the latter two could be performed at a clinic built under the exemption but the former could not.

In particular, there is no reason to require higher plumbing and ventilation standards for primary care clinics that provide abortion services than those that do not. In the first place, there is almost no risk of infection from either medication or aspiration abortions. The rate of post-abortion infection is extremely rare, even in a high-risk population. The published rate of post-operative infections following all out-patient abortions, including surgical abortions, is 0.1-.04%.[1] A recent study of aspiration abortions in California reported only 14 infections out of 11,487 abortions (0.12%).[2]

Second, as set forth in the attached letters from several Medical Directors of PPAC's affiliates, there is no evidence that ventilation or plumbing factors play any role in causing infection.[3] There is no reason why plumbing would have any effect on infection risk. Airborne infections (due to inadequate ventilation) are not the mechanism of infection. As described in the attached letter from Dr. Jennefer Russo, Medical Director of Planned Parenthood of Orange and San Bernardino Counties, almost all infections are introduced mechanically during the procedure.[4]

**There is No Regulatory Reason for Excluding Primary Care Clinics that Provide Abortion Services from the Exemption**

At various times, OSHPD has proffered various reasons for excluding 1226.7 from the exemption. None have merit.

For example, OSHPD claimed that it could not include primary care clinics that provided early abortion services because of national building standards. We found nothing in those standards that draws this distinction and, ultimately, OSHPD seemed to retract this position.

Next, OSHPD claimed that it needed to differentiate primary care clinics described in 1226.6 from those that provide abortion services because of Title 22 requirements. Nothing in Title 22 mandates this result. The sections of Title 22 that refer to abortion services, sections 75040-75044, contain no discussion of heightened mechanical or plumbing requirements. There is, therefore, no

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[1] Letter from Dr. Mary Gatter to Glenn S.A. Gall, AIA (Feb. 1, 2013), attached as Tab A

[2] Weitz et al., "Safety of Aspiration Abortions Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants under a California Legal Waiver," at e4 *American Journal of Public Health* (published online ahead of print Jan. 17, 2013). For OSHPD's convenience, we have attached a copy of this study at Tab B.

[3] Letter from Jeff Waldman, MD, to Glenn S.A. Gall, AIA (Feb. 26, 2013); letter from Richard L. Fischer, MD, to Glenn S.A. Gall, AIA (Feb. 4, 2013); letter from Virginia Siegfried, MD (Feb. 1, 2013); letter from Jennefer Russo, MD, MPH, to Glenn S.A. Gall, AIA (Feb. 3, 2013), attached at Tab C.

[4] Letter from Jennefer Russo, MD, MPH, to Glenn S.A. Gall, AIA (Feb. 3, 2013)(Tab C); *see also* letter from Dr. Mary Gatter to Glenn S. A. Gall, AIA (Feb. 1, 2013)(Tab A).

reason why Title 22 should preclude the inclusion of primary care clinics that provide medication and aspiration abortions in the OSHPD 3SE exemption.

The fact that Title 22 separately mentions abortion services is irrelevant. As with the separate reference to abortion in Title 24, these provisions were added decades ago before medication abortion emerged as a safe and effective method for terminating pregnancies up to 8 or 9 weeks. Together with the resurgence of aspiration abortion in the mid-1990's as a safe, effective option for early abortions, these two procedures allowed free standing clinics to become the dominant place for abortion delivery in California and the United States. The distinction between primary care clinics that perform abortion services and those that do not is now anachronistic.

Finally, OSHPD claimed some unnamed OB-GYN at the Department of Public Health indicated a need for these additional plumbing and mechanical code provisions. In response, Planned Parenthood submitted letters from five Medical Directors who collectively oversee over 75 health centers scattered throughout the state. They unanimously agreed that there is *no evidence* that plumbing and mechanical affect the risk of infection. OSHPD never rebutted these submissions, presumably because it could not.

**Refusal to include primary care clinics that provide abortion services within the exemption is unconstitutional**

The California Constitution strongly protects access to abortion. As the California Supreme Court has said: "By virtue of the explicit protection afforded an individual's inalienable right of privacy by article I, § 1 of the California Constitution, . . . the decision whether to bear a child or to have an abortion is so private and so intimate that each woman in this state – rich or poor – is guaranteed the constitutional right to make that decision *as an individual*, uncoerced by governmental intrusion."[5] The California Legislature reaffirmed the Court's holding when it declared as the State's public policy: "Every woman has the fundamental right to choose to bear a child or to choose and to obtain an abortion."[6] To safeguard women's childbearing decisions, California courts closely scrutinize restrictions placed on abortion providers because they significantly affect access to abortion. Again, as the California courts have said: "'[T]he Legislature need not subsidize any of the costs associated with childbearing, or with health care generally . . . once it chooses to enter the constitutionally protected area of choice, it must do so with genuine indifference. It may not weight [sic] the options open to the pregnant woman by its allocation of public funds; in this area, government is not free to 'achieve with carrots what [it] is forbidden to achieve with sticks.'"[7]

By differentiating between primary care clinics that provide early abortion services and those that do not, the proposed exemption violates the California Constitution and the Supreme Court's

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[5] *Committee to Defend Reproductive Rights v. Myers,* 29 Cal. 3d 252, 284 (1981)(emphasis in original)(holding that state law limiting MediCal funding of abortions violated privacy and equal protection guarantees of California Constitution).

[6] Health & Safety Code § 123462(b).

[7] *Planned Parenthood of Santa Barbara v. City of Santa Maria,* 16 Cal. App. 4th 685, 693 (1993)(finding that restrictions on providing abortion imposed as a condition of receiving funds for clinic construction unconstitutional), *quoting Committee to Defend Reproductive Rights,* 29 Cal. 3d at 285.

mandate. It curtails the ability of women to access abortion services by making the cost of constructing clinics that provide them significantly more expensive. And it does so with no medical or other defensible justification. The State does not require doctors and other licensed clinicians in private practice who provide early abortion services to outfit their facilities with special, expensive plumbing and ventilation. Nor, if the exemption is enacted, will it require primary care clinics that perform nearly identical procedures to meet the heightened standards. If these requirements were necessary to protect the health of women accessing early abortion, private patients would have experienced infections, and the State would have imposed these regulations.

Where, as here, there is a significant infringement on a woman's "intimate and fundamental constitutional right to choose whether or not to continue her pregnancy," the burden shifts to the state to prove it has a compelling interest in the regulation, it is the least intrusive alternative available and it is "so narrowly drawn as to impinge upon the constitutionally protected area no more than is necessary to accomplish the state's legitimate goals."[8] Here, this cannot be done. There is no interest, much less a compelling one, in requiring primary care clinics that offer early abortions to comply with more costly building standards.

There is a simple fix to this problem. The Building Standards Commission can amend the proposed exemption to include § 1226.7. This fix will fulfill OSHPD's stated goal of facilitating the construction of new primary care clinics. It will fulfill the state's goal of improving access to health care. Seventy percent of abortions in California are performed in community clinics yet 52% of California counties have no accessible abortion provider. This year, Assembly Member Atkins is proposing AB 154 to address the current shortage of health care professionals able to provide early abortion care in California. This goal will be completely undermined if primary care clinics that include early abortion services are subjected to prohibitively expensive and unnecessary building standards. By expanding the exemption, new clinics can be built or abortion services added, helping to increase access to early abortion.

For all these reasons, we request that the Building Standards Commission amend the proposed exemption to include §1226.7 (i.e. clinics providing abortion services where treatment rooms are sized as examination rooms, as described in § 1226.7.1) and approve the exemption as amended.

[8] *American Academy of Pediatrics v. Lungren,* 16 Cal. 4th 307, 323 (1997).

# TAB "A"

Planned Parenthood
Los Angeles

February 1, 2013

Glenn S.A. Gall, AIA
Regional Supervisor, Building Standards Unit
Office of Statewide Health Planning and Development
Facilities Development Division
400 R Street, Suite 200
Sacramento, CA 95811

Dear Mr. Gall:

I am a Board-Certified ObGyn physician and the Medical Director of Planned Parenthood in Los Angeles. I am a graduate of the Harvard Medical School and its associated ObGyn residency program, with over thirty years' experience in providing reproductive health care in clinic settings. I also provide consultative services in this area both nationally and internationally.

I am writing in support of including health clinics that provide abortion services in the sites covered by OSHPD 3SE. I have seen the letter written by Dr. Peipert, an expert in this field, and I agree completely with him that infection rates related to abortions, which are already quite low, are associated with pre-existing patient conditions (such as having an STD, or being immuno-compromised) or to poor surgical technique, but not in any way to physical considerations such as plumbing or airflow.

Several large meta-analyses have concluded that infection rates following abortion are best reduced with the use of prophylactic antibiotics, and this is a practice which we employ. The published rate of post-operative infections following out-patient abortion is 0.1-0.4%. I can conclude from this low rate that serious infectious events do not occur with any great frequency in a surgical abortion practice that employs appropriate surgical technique and the use of prophylactic antibiotics.

At Planned Parenthood Los Angeles our top priority is patient safety, however, differential treatment of health clinics that perform abortions does nothing in pursuit of this goal. I would urge OSHPD to reconsider the exclusion of abortion providing clinics from the OSHPD 3SE category.

Sincerely Yours,

Dr. Mary Gatter
Medical Director

cc: Robert P. David, Director of the Office of Statewide Health Planning and Development.

# TAB "B"

# Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver

Tracy A. Weitz, PhD, Diana Taylor, PhD, Sheila Desai, MPH, Ushma D. Upadhyay, PhD, Jeff Waldman, MD, Molly F. Battistelli, BA, and Eleanor A. Drey, MD

*Objectives.* We examined the impact on patient safety if nurse practitioners (NPs), certified nurse midwives (CNMs), and physician assistants (PAs) were permitted to provide aspiration abortions in California.

*Methods.* In a prospective, observational study, we evaluated the outcomes of 11 487 early aspiration abortions completed by physicians (n = 5812) and newly trained NPs, CNMs, and PAs (n = 5675) from 4 Planned Parenthood affiliates and Kaiser Permanente of Northern California, by using a noninferiority design with a predetermined acceptable risk difference of 2%. All complications up to 4 weeks after the abortion were included.

*Results.* Of the 11 487 aspiration abortions analyzed, 1.3% (n = 152) resulted in a complication: 1.8% for NP-, CNM-, and PA-performed aspirations and 0.9% for physician-performed aspirations. The unadjusted risk difference for total complications between NP–CNM–PA and physician groups was 0.87 (95% confidence interval [CI] = 0.45, 1.29) and 0.83 (95% CI = 0.33, 1.33) in a propensity score–matched sample.

*Conclusions.* Abortion complications were clinically equivalent between newly trained NPs, CNMs, and PAs and physicians, supporting the adoption of policies to allow these providers to perform early aspirations to expand access to abortion care. (*Am J Public Health.* Published online ahead of print January 17, 2013: e1–e8. doi:10.2105/AJPH.2012.301159)

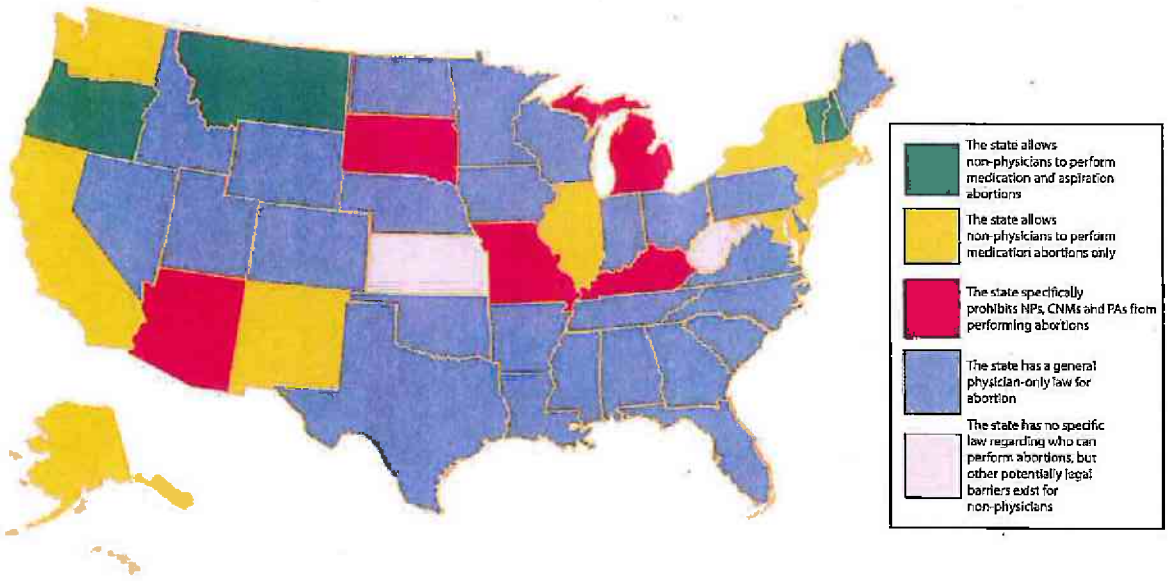
Increased access to early abortion is a pressing public health need. By 2005, the number of abortion care facilities in the United States had decreased 38% from its peak in 1982.[1] Although the number has since remained stable, the proportion of US counties with no facility remains high at 87%; more than one third of women aged 15 to 44 years live in these counties.[2] Additionally, a large proportion of US facilities are hospitals that perform abortions only in cases of serious medical and fetal indications or facilities that offer medical abortions only up to 9 weeks of pregnancy.[2]

Many women face difficulties finding a facility, resulting in delayed care.[3] Increasing access is critical because abortions at later gestations are associated with a higher risk of complications[4] and higher costs.[2] Research has also found that many women would prefer to obtain their abortions earlier.[5] Finally, traditionally underserved populations experience the greatest barriers to abortion care, resulting in higher rates of procedures after the first trimester.[6,7]

In California, more than half of the 58 counties lack a facility that provides 400 or more abortions (R. K. Jones, personal communication). Low-income and minority women are most likely to be served by public health departments or community health centers,[8] most of which do not provide abortions. These women are also more likely to be cared for by nurse practitioners (NPs) and physician assistants (PAs) than by obstetricians and gynecologists.[9]

One potential solution to improve access is to increase the number and types of health care professionals who offer early abortion care.[10–12] Increased emphasis has been placed on task sharing to better meet women's health needs in the context of health care workforce shortages.[13] In the United States, health professions are regulated through a patchwork of state regulations[14,15] that determine who can perform abortions, a power reaffirmed by several US Supreme Court decisions.[16–18] Currently, nonphysician clinicians can perform aspiration abortions legally in only 4 states—Montana, Oregon, New Hampshire, and Vermont. Two additional states (Kansas and West Virginia) do not limit the performance of abortions to physicians, but nonphysician clinicians have never tried to provide abortion care. Of the remaining 44 states (Figure 1), some allow nonphysician clinicians to perform medical (but not aspiration) abortions under decisions by attorneys general or health departments, and 1 state—California—passed statutory authority for that care. As part of a larger effort to limit abortion access, several states have recently promulgated laws that specifically prohibit nonphysician clinicians from performing abortions.[19] For example, a 2009 Arizona law (HB 2564 and SB 1175) that precluded NPs from providing abortions resulted in the discontinuation of abortion care at several facilities that had previously been staffed exclusively by NPs.[20]

Limited clinical evidence is available to inform policymakers about whether physician-only legal restrictions on abortion are evidence-based.[21–24] Our study was designed to provide this evidence to policymakers; it answers the question "What would be the impact on patient safety if NPs, PAs, and certified nurse midwives (CNMs) were permitted to provide aspiration abortions in California?" (We use the term *aspiration abortion* to refer to what is commonly called *surgical abortion* because the technique does not meet the technical definition of surgery.[25]) We used a noninferiority design to compare the incidence of abortion-related complications between groups because we anticipated a slightly higher number of complications among newly trained NPs, CNMs, and PAs than among the experienced physicians.




*Note.* CNM = certified nurse midwife; NP = nurse practitioner; PAs = physician assistants.

**FIGURE 1—Landscape of health professional regulation of abortion provision in the United States.**

## METHODS

In 2005, study investigators applied to the California Office of Statewide Health Planning and Development (OSHPD) for a waiver of legal statutes that limit the completion of surgical abortion to physicians.[26–28] Following a public meeting, hearing, and extensive input from stakeholders, the State of California granted approval for Health Workforce Pilot Project No. 171 in March 2007, followed by approval of 4 subsequent extensions. The study received institutional review board approvals from the University of California, San Francisco; Ethical and Independent Review Services; and Kaiser Permanente of Northern California (KPNC).

In this prospective, observational cohort study, NPs, CNMs, and PAs from 5 partner organizations (4 Planned Parenthood affiliates and KPNC) were trained to competence in the provision of aspiration abortion (a minimum of 40 procedures over 6 clinical days, with competence assessed by an authorized physician trainer). To be qualified for training, NPs, CNMs, and PAs had to have a California professional license, basic life support certification, and 12 months or more of clinical experience, including 3 months or more experience in medication abortion provision. Physicians employed by the facility served as the comparison group. A total of 28 NPs, 5 CNMs, and 7 PAs (n = 40) and 96 physicians (with training in either family medicine or obstetrics and gynecology) completed procedures during the study period. Physicians had a mean of 14 years of experience providing abortions compared with a mean of 1.5 years among NPs, CNMs, and PAs. This analysis did not include procedures performed by NPs, CNMs, and PAs during their training phase.

Patients were enrolled at 22 clinical facilities between August 2007 and August 2011. Patients were eligible for the study if they were aged 16 years or older (18 years at Planned Parenthood affiliates), were seeking a first-trimester aspiration abortion (facilities self-defined this as ≤ 12 or ≤ 14 weeks' gestation by ultrasound), and could speak English or Spanish. Patients were excluded if they requested general anesthesia or did not meet the health-related criteria (unexplained historical, physical, or laboratory findings or known or suspected cervical or uterine abnormalities).

### Study Procedures

Eligible patients reviewed a consent form with a facility staff member. If a patient agreed to participate, she was asked whether she was willing to have her abortion done by an NP, CNM, or PA; if so, the aspiration was performed by the NP, CNM, or PA on duty. Patients in this group were routed to a physician if clinical flow necessitated reorganizing patients. Patients were also routed to a physician if they were unwilling to have their abortions performed by an NP, CNM, or PA or arrived for care when only a physician was present.

Each patient received $5 and a follow-up survey about medical problems after the abortion to capture any delayed postprocedure complications. If patients did not return the survey, clinic staff made at least 3 attempts to administer the survey by phone. If the patient experienced postabortion problems, she was asked a defined set of questions to obtain medical details. Additionally, staff conducted patient chart abstractions 2 to 4 weeks after abortion to ensure delayed complications were

captured. For all outcomes other than an uncomplicated recovery, an incident report was generated and reviewed by the site medical director, study investigators, and the study's Data and Clinical Safety Monitoring Committee. Additional monitoring of outcomes and study procedures included annual Office of Statewide Health Planning and Development–sponsored site visits; quarterly reviews of participant recruitment, patient experience, and clinical outcomes; and routine communication between facility and UCSF study staff.

### Study Outcomes

Unlike a superiority analysis, a noninferiority study design determines whether the effect of a new treatment is not worse than that of an active control by more than a specified clinically acceptable margin.[29–32] We selected a noninferiority design because we were seeking not to replace physicians as abortion providers or to determine whether NPs, CNMs, and PAs were better than current providers of care but to identify additional, comparably safe providers to supplement the provider pool. Because NPs, CNMs, and PAs who are newly trained in aspiration abortion have less experience, we expected to find a statistically significant higher rate of complications among this group than among more experienced physicians. However, we also anticipated a low overall incidence of complications from procedures across both groups. Therefore, a noninferiority design provided a more clinically relevant analysis. Given a low expected complication rate in both provider groups, we prespecified the margin of noninferiority as a change of 2%, which was determined before the start of the study by a panel of researchers and clinicians and approved by the Data and Clinical Safety Monitoring Committee, who considered ethical and clinical issues and previous US-based studies, which showed abortion-related complication rates ranging from 1.3% to 4.4%.[21,22,33–38]

The primary outcome was the difference in incidence of complications within 4 weeks of the aspiration abortion between NPs, CNMs, and PAs and physicians. Complications were categorized as immediate (occurring before leaving the facility) and delayed (occurring ≤ 4 weeks after the procedure). Additionally, complications were classified as major if the patient required hospital admission, surgery, or a blood transfusion and minor if they were treated at home or in an outpatient setting. This classification schema is consistent with that used in other studies of abortion-related morbidity.[34–37]

### Statistical Analysis

We based sample size calculations for this study on an expected complication rate of 2.5%, which was based on mean complication rates cited in the published literature[21,22,33–38] and powered at 90% to detect a 1.0% or greater difference in complication incidence between groups ($\alpha = .025$, 1-tailed test). The study was powered specifically for a noninferiority analysis. Although we set a clinically acceptable margin of difference at 2.0%, we took a conservative approach and powered the study to detect an even smaller difference. We then further increased the sample size per group by 15% to adjust for clustering effects at the provider and clinic levels.

We compared sociodemographic characteristics of patients seen by NPs, CNMs, and PAs and those seen by physicians using mixed-effects logistic regression for dichotomous variables, mixed-effects multinomial logistic regression for categorical variables, and mixed-effects linear regression for continuous variables, all of which included random effects for facility. Incidence of a complication was coded as a dichotomous variable. Complication incidence was calculated by provider group. We fit a mixed-effects logistic regression model with crossed random effects to obtain odds ratios that account for the lack of independence between abortions performed by the same clinician and within the same facility and cross-classification of providers across facilities. We included variables associated with complications in bivariate analyses at $P < .05$ in the multivariate model in addition to other clinically relevant covariates to adjust for potential confounders.

To mitigate selection bias resulting from the lack of randomization, we replicated the analysis in a propensity score–matched sample, a method used to achieve balance between study groups in observational or nonrandomized studies using the predicted probability of group membership (NP, CNM, or PA vs physician group) on the basis of observed predictors.[39–41] We used the Stata module pscore to develop the propensity scores based on a logistic regression model that included patient characteristics that potentially influenced to which provider type the patient was assigned (age, race/ethnicity, insurance type, gestational age, parity, history of cesarean delivery, history of miscarriages, history of abortions, screening for sexually transmitted infections, positive test for a sexually transmitted infection, selection of a clinical contraceptive method, and presence of risk factors). Patients with similar propensity scores in the 2 provider groups were matched using nearest neighbor matching. After testing that the balancing property of the propensity score was satisfied, we selected a matched sample composed of 78.3% of the original sample, among which we replicated our mixed-effects analysis. We used predictive probabilities to calculate risk differences and 95% confidence intervals (CIs) for all models. We used STATA version 12 (StataCorp LP, College Station, TX) for all analyses.

## RESULTS

A total of 21 095 women were screened for eligibility. Of these, 3837 did not meet the eligibility criteria, most commonly because of patient age and gestational age. Among the 17 258 eligible women, 13 807 agreed to participate in the study. Of these, 2320 had procedures performed by NPs, CNMs, and PAs during their training phase and were therefore not included in this analysis. As a result of a protocol violation at 1 site, 79 patients in the physician group were excluded. Follow-up data were available for 69.5% of patients, and follow-up rates were nondifferential between provider groups. Patients who did not return the follow-up survey were retained in the analytic sample because we found that they contacted the facility when they did experience a complication ($n = 41$), which we also discovered via medical chart abstraction, suggesting a low likelihood of missing complications among this group. Additionally, in a sensitivity analysis, complication incidence and risk differences were similar when we excluded patients who did not return the

**TABLE 1—Baseline Characteristics of Patient Study Participants by Provider Type at 22 California Clinical Facilities: August 2007–August 2011**

| Patient Characteristic | Physicians (n = 5812), % or Mean ±SD | NPs-CNMs-PAs (n = 5675), % or Mean ±SD | P[a] |
|---|---|---|---|
| Age, y | 25.7 ±6.1 | 25.8 ±5.9 | .01 |
| 16–19 | 12.9 | 13.5 | .73 |
| 20–24 (Ref) | 39.0 | 39.0 | |
| 25–34 | 36.9 | 37.4 | .83 |
| ≥35 | 11.2 | 10.1 | .06 |
| Race/ethnicity[b] | | | |
| White, non-Hispanic (Ref) | 29.3 | 29.5 | |
| Black, non-Hispanic | 12.1 | 13.8 | .03 |
| Hispanic | 40.6 | 40.4 | .87 |
| Asian, non-Hispanic | 8.3 | 6.6 | .01 |
| Other, non-Hispanic | 8.7 | 8.5 | .83 |
| Insurance type | | | |
| No coverage (Ref) | 24.7 | 26.5 | |
| Medi-Cal[c] | 56.3 | 54.1 | .68 |
| Private | 11.9 | 14.1 | .67 |
| Other | 7.1 | 5.3 | <.001 |
| Gestational age, d | | | |
| <36 (Ref) | 2.5 | 2.7 | |
| 36–49 | 31.5 | 33.3 | .26 |
| 50–63 | 32.1 | 33.1 | .36 |
| ≥64 | 33.9 | 30.9 | .93 |
| Gravidity | | | |
| ≤1 (Ref) | 27.2 | 26.9 | |
| 2 | 20.6 | 21.5 | .25 |
| 3 | 18.3 | 17.4 | .55 |
| ≥4 | 33.9 | 34.1 | .59 |
| Parity[d] | | | |
| 0 (Ref) | 44.2 | 44.9 | |
| 1 | 24.8 | 24.1 | .63 |
| ≥2 | 30.8 | 30.7 | .97 |
| Previous cesarean deliveries | | | |
| 0 (Ref) | 86.5 | 86.7 | |
| ≥1 | 13.5 | 13.3 | .21 |
| Previous miscarriages[e] | | | |
| 0 (Ref) | 82.3 | 82.7 | |
| 1 | 13.9 | 13.2 | .2 |
| ≥2 | 3.5 | 3.6 | .99 |
| Previous induced abortions[f] | | | |
| 0 (Ref) | 52.3 | 51.5 | |
| 1 | 28.0 | 28.6 | .46 |
| ≥2 | 19.5 | 19.6 | .7 |
| Tested positive for an STI | 3.6 | 3.4 | .77 |

Continued

follow-up survey. Patients without follow-up data were more likely to have no insurance, have fewer risk factors, be multigravida, and be at less than 5 weeks gestation than were those with follow-up data ($P<.05$; not shown). The final analytic sample size was 11 487; of these procedures, 5812 were performed by physicians and 5675 were performed by NPs, CNMs, or PAs.

### Patient Characteristics

The majority of women in both groups had had 3 or more pregnancies; no previous cesarean deliveries, miscarriages, or induced abortions; and no history of medical risk factors (Table 1). Women in the NP–CNM–PA group were more likely to be younger ($P<.01$), less likely to be Asian than White ($P<.01$), and more likely to be non-Hispanic Black than White ($P<.03$). Women were similar on all other sociodemographic characteristics across provider groups.

### Outcomes

Overall, complications were rare (Table 2). Out of 11 487 aspiration abortions, 1.3% (n = 152; 95% CI = 1.11, 1.53) resulted in a complication; 1.8% of NP-, CNM-, and PA-performed aspirations and 0.9% of physician-performed aspirations resulted in a complication. The majority of complications (146/152, or 96%) were minor (1.3% of all abortions) and included cases of incomplete abortion (n = 9 among physicians, n = 24 among NPs, CNMs, and PAs), failed abortion (n = 7 among physicians, n = 11 among NPs, CNMs, and PAs), bleeding not requiring transfusion (n = 2 among NPs, CNMs, and PAs), hematometra (n = 3 among physicians, n = 16 among NPs, CNMs, and PAs), infection (n = 7 among physicians, n = 7 among NPs, CNMs, and PAs), endocervical injury (n = 2 among physicians, n = 2 among NPs, CNMs, and PAs), anesthesia-related reactions (n = 1 among physicians, n = 1 among NPs, CNMs, and PAs), and uncomplicated uterine perforation (n = 3 among NPs, CNMs, and PAs). We classified complications without clear etiology but accompanied by patient symptoms as symptomatic intrauterine material (n = 16 among physicians, n = 24 among NPs, CNMs, and PAs). We classified 11 minor complications as "other"; 4 were from physician-performed procedures

**TABLE 1—Continued**

| | | | |
|---|---|---|---|
| Risk factors[6] | | | |
| Extreme obesity (BMI > 40 kg/m$^2$) | 2.3 | 2.2 | .33 |
| Existing chronic illness | 5.0 | 4.9 | .72 |
| Placenta previa (16-18 wk) | 0.0 | 0.0 | .32 |
| Psychiatric condition | 3.3 | 3.2 | .61 |

*Note.* BMI = body mass index; CNM = certified nurse midwife; NP = nurse practitioner; PA = physician assistant; STI = sexually transmitted infection. Physicians had completed a residency in either obstetrics and gynecology or family medicine. Missing data on age (n = 18), patient insurance (n = 35), cesarean delivery history (n = 82), and gravidity (n = 7) were recoded to mean age, no insurance, no history of cesarean delivery, and median gravidity, respectively. Missing data on gestational age by ultrasound (n = 85) were recoded to gestational age by last menstrual period; where those data were also missing, they were recoded to the mean gestational age by ultrasound. For other missing variables, we created a new variable for missing.
[a]*P* values are based on a significance level of .05 and were calculated using mixed-effects logistic regression for dichotomous variables, mixed-effects multinomial logistic regression for categorical variables, and mixed-effects linear regression models for continuous variables, all of which included random effects for facility.
[b]Data missing for 70 women in the NP-CNM-PA group and 56 in the physician group.
[c]California's Medicaid program.
[d]Data missing for 11 women in each provider group.
[e]Data missing for 25 women in the NP-CNM-PA group and 20 in the physician group.
[f]Data missing for 17 women in the NP-CNM-PA group and 18 in the physician group.
[g]All risk factor variables are dichotomous (no-yes). "No" is the reference category (not shown in table).

(1 urinary tract infection, 1 possible false passage, 1 probable gastroenteritis, 1 unspecified allergic reaction), and 7 were from NP-, CNM-, or PA-performed procedures (1 fever of unknown origin, 1 intrauterine device–related bleeding, 3 sedation drug errors, 1 inability to urinate, 1 vaginitis).

Only 6 major complications occurred (3 in each provider group), which included 2 uterine perforations, 3 infections, and 1 hemorrhage. We found no difference in risk of major complications between provider groups: 0.001% (95% CI = −0.08, 0.09).

The overall unadjusted risk difference for total complications between NPs, CNMs, and PAs and physicians was 0.87% (95% CI = 0.45, 1.29). The risk difference in immediate complications (n = 9 for physicians; n = 20 for NPs, CNMs, and PAs) was 0.20% (95% CI = 0.01, 0.38); for delayed complications (n = 43 for physicians; n = 80 for clinicians), it was 0.67% (95% CI = 0.29, 1.10).

Abortions by NPs, CNMs, and PAs were 1.92 (95% CI = 1.36, 2.72) times as likely to result in a complication as those performed by physicians after adjusting for potential confounders (see table available as a supplement to the online version of this article at http://www.ajph.org). Among the propensity score–matched sample, complications were 2.12 (95% CI = 1.33, 3.37) times as likely to result from abortions by NPs, CNMs, and PAs as by physicians. The corresponding risk differences were 0.70% (95% CI = 0.29, 1.10) in overall complications between provider groups in the adjusted model and 0.83% (95% CI = 0.33, 1.33) in the propensity score–matched sample. The estimated 95% CIs for risk differences in unadjusted, adjusted, and propensity score–matched analyses all fell well within the predetermined margin of noninferiority, and therefore complication rates from aspiration abortions performed by recently trained NPs, CNMs, and PAs were statistically no worse than those from those performed by the more experienced physician group (Figure 2).

## DISCUSSION

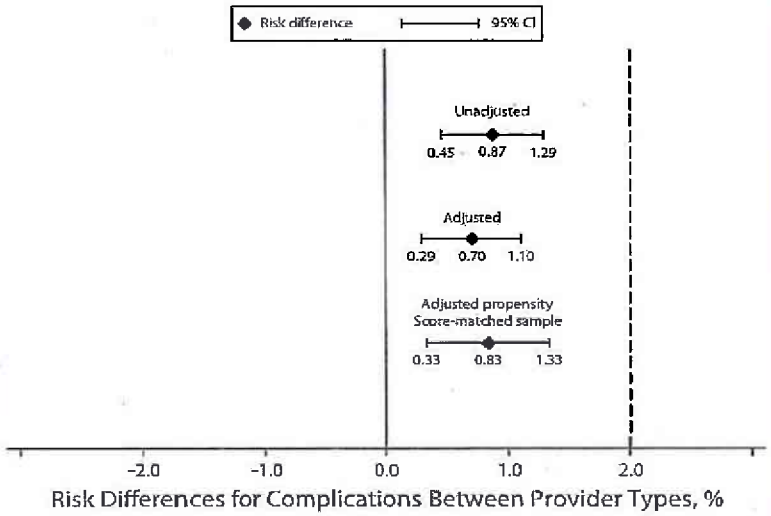
In 2008, 1.21 million abortions took place in the United States, with more 200 000 (18%) in the State of California.[2] Nationally, 92% of abortions take place in the first trimester,[7] but Black, uninsured, and low-income women have less access to this care.[8] In California, only 87% of women using state Medicaid insurance obtain abortions in the first trimester.[12] Because the average cost of a second-trimester abortion is substantially higher than that of a first-trimester procedure, shifting the population distribution of abortions to earlier gestations would result in safer, less costly care. Increasing the types of health care professionals involved in abortion care is one way to reduce this health care disparity.

Our study was designed to examine the effect of removing the physician-only requirement for aspiration abortion provision in California. We found that the care provided by newly trained NPs, CNMs, and PAs was not inferior to that provided by experienced physicians. We estimate that only 1 additional complication would occur for every 120 procedures as a consequence of having an NP, CNM, or PA as the abortion provider. Additionally, the 0.83% risk difference was mainly

**TABLE 2—Overall and Major and Minor Complication Rates by Provider Type at 22 California Clinical Facilities: August 2007–August 2011**

| | Physicians (n = 5812) | | NPs–CNMs–PAs (n = 5675) | | Total (n = 11 487) | | Risk Difference Between Provider Groups (n = 11 487) |
|---|---|---|---|---|---|---|---|
| Complication Type | Rate/100 (95% CI) | No. | Rate/100 (95% CI) | No. | Rate/100 (95% CI) | No. | Difference in Rate/100 (95% CI) |
| Major | 0.05 (−0.01, 0.11) | 3 | 0.05 (−0.01, 0.11) | 3 | 0.05 (0.01, 0.09) | 6 | 0.001 (−0.08, 0.09) |
| Minor | 0.84 (0.61, 1.08) | 49 | 1.71 (1.37, 2.05) | 97 | 1.27 (1.07, 1.48) | 146 | 0.87 (0.46, 1.28) |
| Total | 0.89 (0.65, 1.14) | 52 | 1.76 (1.42, 2.10) | 100 | 1.32 (1.11, 1.53) | 152 | 0.87 (0.45, 1.29) |

*Note.* CI = confidence interval; CNM = certified nurse midwife; NP = nurse practitioner; PA = physician assistant. Physicians had completed a residency in either obstetrics and gynecology or family medicine.




*Note.* CI = confidence interval. Both adjusted models included patient age, race/ethnicity, insurance type, gestational age, gravidity, history of cesarean section, positive test for a sexually transmitted infection, an indicator for extreme obesity, an indicator for chronic illness, and an indicator for psychiatric conditions. 2.0 is also the delta.

**FIGURE 2—Unadjusted, adjusted, and adjusted propensity score–matched risk differences in overall complication rates of first-trimester aspiration abortion by nurse practitioner, certified nurse midwife, and physician assistant providers compared with physician providers in California.**

the result of higher incidence of minor complications, the majority of which were from diagnoses easily treated and without consequential sequelae. Moreover, on the basis of findings in other studies, we expect this risk difference to narrow further over time.[43–45] The comparison of newly trained NPs, CNMs, and PAs with more experienced physician abortion providers suggests that the small difference found would represent the maximum variation in outcomes that might be expected immediately after a policy change.

Both provider groups had extremely low numbers of complications, less than 2% overall—well below published rates—and only 6 complications out of 11 487 procedures required hospital-based care. Because the effect size is minimal compared with the published data and within the prespecified margin of noninferiority, we conclude that the difference between the 2 groups of providers is not clinically significant.

While the reported odds ratios comparing complication rates from procedures performed by NPs, CNMs, and PAs with those from procedures performed by physicians were statistically significant, these results should be interpreted cautiously. The study was powered specifically for a noninferiority analysis, which necessitated a larger sample size than a superiority analysis would. Therefore the significance we see may be a result of the study being overpowered.

These findings support the adoption of policies that increase access to abortion by expanding the number and type of health care professionals who can perform early aspiration abortions. The benefits of expanding access to abortion for California's women outweigh the small initial difference in risk, particularly because it would likely move many second-trimester abortions into the first trimester, significantly decreasing the overall risk of complications, which increases with gestational age.[4] Expanded access is also likely to afford more women the opportunity to obtain care without the additional indirect costs associated with traveling to a geographically distant abortion provider.

The strengths of this study are its statistical power, the large number of providers, and its setting in multiple facilities. A limitation of the study is its nonrandomized design, although the use of propensity score matching allowed for statistical adjustments to address this limitation. Additionally, this study had a low follow-up rate (70%), but this was not unexpected because of the sensitive nature of abortion, which may have deterred women from continuing participation in the study after the procedure. This follow-up rate is also similar to those in other US abortion-related studies with comparable follow-up periods (14–28 days).[22,37,46] Although postprocedure complications may have been missed among patients for whom we did not have follow-up data, given the nondifferential follow-up rates between provider groups, we would expect unidentified complications to be equally distributed between groups, leaving the risk difference unaffected. A further limitation of the study is that the health care provider who initially identified a complication was not blinded to the type of provider who performed the abortion. However, we hypothesize that complaints from patients cared for by newly trained NPs, CNMs, and PAs would be more aggressively evaluated if the provider type was known to the health care provider evaluating the patient. Therefore, any bias caused by lack of blinding would have resulted in an overestimate of the risk difference.

Our results confirm existing evidence from smaller studies that the provision of abortion by NPs, CNMs, and PAs is safe[21,22] and from larger international[13] and national[47] reviews that have found these clinicians to be safe and qualified health care providers. The value of this study extends beyond the question of who can safely perform aspiration abortion services in California because it provides an example of how research can be used to answer relevant health workforce policy issues. As the demand for health care providers increases under US health care reform,[48] one part of the solution for all health care, including abortion care, is to allow all

qualified professionals to perform clinical care to the fullest extent of their education and competency.[49,50] ■

## About the Authors

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## Contributors

T. A. Weitz and D. Taylor developed the study concept and design. T. A. Weitz, D. Taylor, and E. A. Drey supervised the overall study and analyzed the interpretation of results. S. Desai oversaw the acquisition of data. U. D. Upadhyay and S. Desai analyzed the data and provided statistical expertise. T. A. Weitz, U. D. Upadhyay, S. Desai, and E. A. Drey drafted the article, and J. Waldman advised on critical revision of the article for intellectual content. M. F. Battistelli provided administrative, technical, and material support.

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## Human Participant Protection

Study protocol and procedures received institutional review board approvals from the University of California, San Francisco; Ethical and Independent Review Services; and Kaiser Permanente of Northern California.

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February 26, 2013

Glenn S.A. Gall, AIA
Regional Supervisor, Building Standards Unit
Office of Statewide Health Planning and Development
Facilities Development Division
400 R Street, Suite 200
Sacramento, CA 95811

RE: OSHPD 3 community clinic construction standards

Dear Attorney Gall,

Since 1982, I have served as the Medical Director of Planned Parenthood Shasta Pacific, serving over 100,000 Californians a year at 30 sites. In 2006, I was appointed the Senior Director of Clinical Services and Medical Education for the national Planned Parenthood Federation of America (PPFA) and served in that capacity through 2009. Additionally, I am the past President of the PPFA Medical Directors Council and I served on PPFA's National Medical Committee. I am also an Assistant Clinical Professor at the University of California, San Francisco.

On the strength of my professional background and experience, I must firmly state my objection to your office's recent recommendations relative to ventilation in abortion clinics with the objective of reducing infection risk. I would hope that any policies or legislation from the state would be based on scientific evidence. The fact is that the risk of infection after an abortion or uterine evacuation procedure is very low. The less than one percent risk would not be affected by plumbing or ventilation. The intrauterine environment is not at risk for airborne infections. Risk factors for infection in the uterus when a surgical procedure is performed include: 1) infection of the cervix with an organism like *Neisseria gonorrhea* or *Chlamydia trachomatis*; 2) use of unsterile instruments; and 3) failure to use sterile technique during the procedure. Illegal abortion, which would potentially employ the last two risks, will also result in a higher risk of infection. However, I am not aware of any studies or biologic plausibility demonstrating that infection after an abortion is affected by plumbing or ventilation.

Any differential treatment of health clinics that perform abortions makes no clinical sense in terms of infection risk. There is no reason to have a different set of criteria for plumbing or ventilation for these clinical sites than other sites. As an expert in family planning and abortion care, it is my belief that there is **no evidence** that plumbing and ventilation impact infection risk.

If you have any further questions or concerns, please feel free to contact me.

Sincerely,

Jeff Waldman, MD
Medical Director

cc: Robert P. David, Director of the Office of Statewide Health Planning and Development

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February 4, 2013

Glenn S.A. Gall, AIA
Regional Supervisor, Building Standards Unit
Office of Statewide Health Planning and Development
Facilities Development Division
400 R Street, Suite 200
Sacramento, CA 95811

cc: Robert P. David, Director of the Office of Statewide Health Planning and Development.

Re: OSHPD 3SE Community Clinic Construction Standards

Dear Supervisor Gall,

I am writing to ask that abortion clinics be included in the OSHPD 3SE category. I am the Associate Medical Director and Physician Director of Abortion Services for the largest Planned Parenthood affiliate in the country. I am also an Assistant Clinical Professor at UCSF and teach on the abortion service at San Francisco General hospital.

Our infection rate at Planned Parenthood Mar Monte is extremely low as it is on most abortion services. Indeed, we had no significant infections out of more than 6800 abortions in 2012. Most abortion experts agree that infection after abortion is caused by bacteria that already exist in a woman's vagina and rarely due to unsterile instruments. There is no evidence that ventilation or plumbing factors play any role in infection after abortion. Excluding abortion clinics would only increase the costs of abortion without effecting safety. I urge you to revise the 3SE standards to include abortion clinics.

Very truly yours,

Richard L. Fischer, M.D.
Associate Medical Director for OB/GYN

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Glenn S.A. Gall, AIA

Regional Supervisor, Building Standards Unit

Office of Statewide Health Planning and Development

Facilities Development Division

400 R Street, Suite 200

Sacramento, CA 95811

February 1, 2013

RE: OSHPD 3SE Category

Dear Mr. Gall,

I am the Medical Director for the Planned Parenthood Affiliate for Santa Barbara, Ventura, and San Luis Obispo counties. I am writing in support of inclusion of our clinics that provide surgical abortion procedures within the OSHPD 3SE category.

As expertly explained by Dr. Peipert, there is no evidence for requiring more stringent criteria for plumbing and ventilation for these clinics. It has always been recognized that the rate of post-abortal infection is extremely rare, even in a high-risk population. I have been the medical director here for 4 years and we perform approximately 1800 surgical procedures per year. I have not seen one abortion complicated by an infection. Likewise, in my 25 years of private practice, my experience was the same.

Thank you for your consideration in this matter.

Virginia Siegfried MD

Virginia Siegfried, MD
Medical Director
Planned Parenthood of Santa Barbara, Ventura &
San Luis Obispo Counties, Inc.

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February 3, 2013

RE: OSHPD 3 community clinic construction standards

Glenn S.A. Gall, AIA
Regional Supervisor, Building Standards Unit
Office of Statewide Health Planning and Development
Facilities Development Division
400 R Street, Suite 200
Sacramento, CA 95811

Dear Attorney Gall,

My name is Jennefer Russo, and I am the Medical Director of Planned Parenthood of Orange and San Bernardino Counties. I am also a Health Sciences Assistant Clinical Professor in the Department of Obstetrics and Gynecology at University of California, Irvine. My research and clinical background is in family planning. I received my medical degree from George Washington University and my Masters in Public Health from University of Pittsburgh. I recently published an article entitled "Controversies in Family Planning: Postabortal Pelvic Inflammatory Disease" in the journal *Contraception.*

The risk of infection after an abortion or uterine evacuation procedure is quite low: 0.5%. Risk factors for infection include: 1) cervicitis (infection of the cervix with *Neisseria gonorrhea* or *Chlamydia trachomatis*); 2) use of unsterile instruments or lack of sterile technique; and 3) illegal abortion. To my knowledge, there are no studies demonstrating that infection after an abortion is affected by plumbing or ventilation. Almost all infections after this procedure are introduced mechanically during the procedure. Airborne infections (due to inadequate ventilation) are not the mechanism of infection. I can think of no reason that plumbing would have any effect on infection risk.

Thus, any differential treatment of health clinics that perform abortions makes no clinical sense in terms of infection risk. There is no reason to have a different set of criteria for plumbing or ventilation for these clinical sites than other sites. As an expert in family planning, it is my belief that there is **no evidence** that plumbing and ventilation impact infection risk.

If you have any further questions or concerns, please feel free to contact me.

Sincerely,

**Jennefer Russo, MD, MPH**
Medical Director
Planned Parenthood of Orange and San Bernardino Counties
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