

August 2, 2023

Colorado State Medical Board, Colorado State Pharmacy Board, Colorado State Nursing Board 1560 Broadway, Suite 1350 Denver, CO 80202

DELIVERED VIA EMAIL

Re: Rules and Regulations Regarding Generally Accepted Standard of Medicine Practice Regarding Pregnancy-Related Services

To the Colorado State Medical Board, Colorado State Pharmacy Board, and Colorado State Nursing Board:

Physicians for Reproductive Health (PRH) is a physician-led national advocacy organization comprised of various specialties from across the country, including Colorado, working to ensure access to equitable, comprehensive reproductive and sexual health care for the communities we serve using evidence-based science and medicine. We write today in opposition to the proposed rules related to SB190 published on Thursday, July 20, 2023. The proposed rule is not based in science or medicine and will cause significant harm to patients and communities in Colorado.

The Board was tasked with promulgating rules "concerning whether engaging in medication abortion reversal is a generally accepted standard of practice." However, instead of complying with this basic directive the Board established a complaint-based system to review individual cases of so-called "reversal" after it is attempted. The decision to "investigate all complaints related to medication abortion reversal in the same manner that it investigates other alleged deviations from generally accepted standards of medical practice" seeks to mitigate harm after it has already occurred rather than preventing the initial harm and does not determine whether so-called "medication abortion reversal" is part of the standard of care. It also improperly shifts the responsibility of regulation to the patient as it requires patients to first know they have been provided substandard care, know they have been harmed by such care, and then undertake the burden of filing a complaint. Patients do not have the same level of knowledge or training as their medical providers and this power deferential is why the professional boards are charged with regulating practitioners and protecting the patients for whom they care. The draft regulations abrogate the duty to create professional standards and abrogates the duty specifically established in SB190.

Professional medical associations including the American Medical Association (AMA) and American College of Obstetricians and Gynecologists (ACOG) do not support abortion "reversal" as it is not based in science and does not meet clinical standards. Abortion "reversal" is not a medical term. Instead, it is language used by those who are anti-abortion to describe a medically unproven protocol in which a high dose of progesterone is given after the first of the two medications used in medication abortion are administered with the disproven belief that this will "reverse" an abortion.

In December 2019, the results from the first randomized control study (the highest level of scientific study) on abortion "reversal" were published. This study had to be stopped because of significant safety concerns about the so-called reversal regimen, namely heavy bleeding that in some cases required blood transfusion and even emergency surgery. The study concluded that the efficacy of progesterone for nullifying the effects of mifepristone could not be estimated due to these significant safety concerns.

Notably, the American College of Obstetrics and Gynecology (ACOG), which publishes practice guidelines for OB-GYN care including abortion, opposes the practice, stating that "claims of medication abortion reversal are not supported by the body of scientific evidence, and this approach is not recommended in ACOG's clinical guidance on medication abortion." As shown by the failed study referenced above, this approach is not safe, effective, nor is it based on medical evidence.

The Boards proposal to establish an informed consent requirement is inadequate because abortion "reversal" has not been rigorously studied to understand the risks, benefits, or efficacy. As cited above, the only randomized control study was stopped because of significant safety concerns and all other evidence is based on case series which cannot prove cause and effect. The informed consent process in health care ensures patients are given all the information about their health condition, including testing and treatment options, to make decisions about their care. An informed consent process that shares stigmatizing or medically inaccurate information undermines a patient's ability to make decisions about their health care and would clearly not meet the standard required for informed consent.

Members of the Board have an opportunity to ensure policy and practice is based on sound science and medical evidence. SB190 was the first piece of legislation in the nation, which attempted regulate medication abortion reversal and the proposed rule attempts to sidestep the clear directives given to the Board. We urge you to issue a rule concerning whether medication abortion meets generally accepted standards of medical practice.

Respectfully,

Dr. Kristyn Brandi, MD, MPH, FAACOG Board Chair Physicians for Reproductive Health