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California Policy Recommendations for Realizing the Promise of Medication Abortion: How the COVID-19 Public Health Emergency Offers a Unique Lens for Catalyzing Change

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California Policy Recommendations for Realizing the Promise of Medication Abortion: How the COVID-19 Public Health Emergency Offers a Unique Lens for Catalyzing Change

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Abstract: *While the new composition of the United States Supreme Court has raised speculation about the fate of Roe v. Wade, for millions in America the promise of a patient's right to choose an abortion is already a distant illusion.** Decades of work by anti-abortion policymakers has resulted in prohibitive state and federal funding restrictions and widespread clinic closures. But clinicians, advocates, and researchers are optimistic about one way to expand access: medication abortion. Known colloquially as "the abortion pill," medication abortion is poised to significantly increase access for patients everywhere, and particularly for low-income patients and those who live in rural areas far from hospitals and clinics.*

One of the biggest barriers to medication abortion today is a stringent set of FDA regulations implemented under the guise of patient safety protocols, which evidence suggests are not only medically unnecessary but politically motivated. While researchers and advocates have been working to lift these restrictions for years, the unprecedented COVID-19 pandemic has provided unique circumstances for studying how access would be affected if the restrictions were to be permanently lifted.

In California, there are three legislative steps that the state can take to

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** Many abortion rights advocates believe that the election of pro-choice President Joe Biden in November 2020 presents opportunities for codifying protections of a patient's right to choose. Given intense conservative opposition to abortion protections in the current Congress, such executive action would undoubtedly give way to legal action. To avoid the myriad hypothetical situations that could arise, this note will not address those potential avenues and will instead focus on the national legislative and judicial status quo.

ensure that Californians have continued access to abortion as guaranteed by the State Constitution, and to expand access to low-income patients and patients in rural areas. First, the State should support the creation of a centralized database for collecting medication abortion data from across the state while restrictions were lifted. Second, the State should remove the dual-ultrasound requirement for Medi-Cal reimbursement. Third, the State should close a loophole in current policy that prevents minors from obtaining medication abortion via telehealth.

It is clear that politicization of reproductive rights will remain a fixture of civil discourse in America for years to come. At the same time, advances in telehealth technology have already provided a glimpse into a future where patients are able to access the reproductive care they need. As a national leader in reproductive justice efforts, California has the opportunity to create lasting impact by exploring efforts to expand access to key patient populations and prepare for a future of true reproductive justice.

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I. INTRODUCTION

Medication abortion (MAB), commonly referred to as the "abortion pill," is a safe and effective method of self-managed abortion.[1] MAB has become an increasingly popular choice among patients seeking both therapeutic and elective abortions. More than four million women have used MAB to end an early pregnancy in the United States.[2] Now the most commonly used method of abortion for pregnancies up to ten weeks' gestation, MAB accounted for sixty percent of all such abortions in the United States in 2017.[3] Patients opt for MAB over surgical procedures for a variety of reasons, chief among them the privacy, comfort, and convenience of passing a pregnancy at home, which often comes with the support of friends or family.

In addition to these patient benefits, clinicians, advocates, and experts across the country celebrate MAB for its power to expand access to low-income patients and patients living in rural areas.[4] But this power remains largely inhibited by federal dispensation requirements, costly components of care delivery, low reimbursement rates for providers, and, importantly, obstruction by anti-abortion politicians. Among many other gaps in the U.S. health care system, these barriers to MAB provision have been highlighted by the COVID-19 public health emergency.

MAB involves a pill regimen of two medications, mifepristone (brand name Mifeprex) and misoprostol (brand name Cytotec, among others), prescribed by a clinician and ingested successively.[5] First, mifepristone blocks the body's production of progesterone, the hormone necessary for a pregnancy to develop, effectively terminating the pregnancy.[6] Taken up to forty-eight hours later, misoprostol then causes uterine contractions and cervical dilation, ultimately expelling the contents of the uterus.[7] Federal law requires that the pills be dispensed to patients by a clinician, but depending on state laws, ingestion takes place in the presence of the prescribing clinician

[1] Megan Donovan, *Medication Abortion and the Changing Abortion Landscape*, GUTTMACHER INST., https://www.guttmacher.org/article/2019/09/medication-abortion-and-changing-abortion-landscape (last visited Mar. 8, 2021).

[2] Extrapolated from the FDA's "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018," which found that 3.7 million women had used mifepristone to end a pregnancy in the United States through the end of 2018. *Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018*, FDA, https://www.fda.gov/media/112118/download (last visited Mar. 9, 2021).

[3] Donovan, *supra* note 1.

[4] *Id.*

[5] *The Abortion Pill*, PLANNED PARENTHOOD, https://www.plannedparenthood.org/learn/abortion/the-abortion-pill (last visited Mar. 13, 2021).

[6] *Id.*

[7] *Id.*

or at a time and location of the patient's choosing.[8,9] In California, the patient may ingest the pills at a time and location of their choice.[10] For the purposes of this note, I will focus almost exclusively on mifepristone because it is heavily restricted by the United States Food and Drug Administration (FDA).[11] Misoprostol is commonly prescribed for uses other than MAB, including inducing labor and ripening the cervix before medical procedures, and is thus far less heavily restricted.[12]

The COVID-19 public health emergency has highlighted disparities and opportunities for increasing access to MAB in California. The disparities are evident in reduced access for vulnerable patient populations due to increased financial hardship and diminished access to care. The opportunities lie in the fact that the temporarily relaxed in-person restrictions for MAB provisions created a window for understanding what the future of MAB could look like. This note considers the current landscape of MAB and ultimately provides three recommendations for actions California can take to ensure maximum and continuous access to MAB beyond the COVID-19 public health emergency: first, the State should foster collection and analysis of no-touch MAB and TeleMAB (MAB prescribed via telehealth) data collected while the FDA's in-person requirements were lifted.[13] Second, the State should remove the costly dual-ultrasound requirement for Medi-Cal reimbursement.[14] Third, the State should close a loophole in current telehealth policy that would prevent minors from accessing TeleMAB services.[15]

This note begins by providing an introduction to the FDA's restrictions of MAB and its arguably politically motivated restrictions at the federal level.[16] It also traces a brief history of MAB access during the COVID-19 pandemic, setting the stage for understanding how the temporary removal of

[8] *Mifeprex (mifepristone) Information*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information (last visited Mar. 8, 2021) [hereinafter FDA, *Mifepristone Information*].

[9] PLANNED PARENTHOOD, *supra* note 5; *The Availability and Use of Medication Abortion*, KAISER FAM. FOUND. (June 8, 2020), https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/.

[10] *State Laws and Policies: Medication Abortion*, GUTTMACHER INST. (updated Mar. 1, 2021), https://www.guttmacher.org/state-policy/explore/medication-abortion (listing states that require physicians to administer medication abortion and states that require the clinician to be physically present when the medication is administered).

[11] *See* FDA, *Mifepristone Information*, *supra* note 8.

[12] Rebecca Allen & Barbara M. O'Brien, *Uses of Misoprostol in Obstetrics and Gynecology*, REV. OBSTETRICS & GYNECOLOGY, Summer 2009, at 159.

[13] *See infra* section II.C.

[14] *See infra* section III.C.

[15] *See infra* section IV.B.

[16] *See infra* section II.A.

in-person requirements may have affected access for Californians.[17] Next, this note discusses restrictions on public funding at the federal and state level that decrease access for low-income and rural patients—and specifically, how the impacts of California's low reimbursement rates can be mitigated by removing the ultrasound requirement for MAB.[18] Finally, this note finishes by proposing a solution for a loophole currently preventing minors from accessing TeleMAB in California.[19]

II. BACKGROUND: THE FDA'S REGULATION OF MIFEPRISTONE AND THE EFFECTS OF COVID-19

A major barrier to MAB access across the country is a set of federal restrictions the FDA places on the prescription and dispensation of mifepristone. A true expansion of MAB access necessitates the permanent removal of these restrictions. While many states place additional restrictions on MAB, California has few and is thus an ideal setting for understanding gaps and opportunities that exist in the push for expanding access. COVID-19 catalyzed a chain of events that allows for this analysis.

A. The FDA's REMS for Mifepristone are Motivated by Politics, Not Patient Safety

As mentioned above, MAB involves a pill regimen of two medications: mifepristone and misoprostol, ingested successively.[20] This section examines each of the Risk Evaluation and Mitigation Strategy (REMS) restrictions that the FDA imposes on mifepristone to underscore expert assessments that they are not medically necessary. According to the FDA, REMS are designed to help reduce the "occurrence or severity of a particular serious adverse event."[21] The below exploration is based largely on the substance of plaintiffs' argument in *Chelius v. Azar*, an ongoing federal lawsuit brought on behalf of a Hawai'i doctor and several professional health care organizations.[22] *Chelius* challenges the constitutionality of the REMS as placing significant burdens, with no medical basis, on women seeking

[17] *See infra* section II.B.
[18] *See infra* section III.A-C.
[19] *See infra* section IV.A-B.
[20] PLANNED PARENTHOOD, *supra* note 5.
[21] *Frequently Asked Questions About REMS*, U.S. FOOD & DRUG ADMIN. (Jan. 26, 2018), https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems.
[22] Complaint at 19, Chelius v. Wright, 2017 WL 4401999 (D.Hawai'i).

medication abortions.[23] The plaintiffs' case relies heavily on data from the FDA's own 2016 medical review of Mifeprex.[24] Abortion advocates hope that the outcome of this case will lead to a permanent removal of the REMS restrictions.

In 2000, the FDA approved Mifeprex for use up to forty-nine days into a pregnancy (today it is approved for up to seventy days).[25] Despite a substantial safety record of data from U.S. trials and European markets, the FDA assigned three significant REMS restrictions to the drug as a condition of approval: explained in detail below, two restrictions require a patient to present in person for prescription and dispensation, and the other requires providers to submit specific documentation to the drug manufacturer.[26] After the FDA determines that a REMS is necessary and specifies the requirements, the drug manufacturer is then responsible for developing and implementing the program.[27] The FDA may later release or lift certain components of a REMS if it determines that the extra measures are no longer necessary to ensure a medication's benefits outweigh its risks.[28]

The most burdensome types of REMS are "Elements to Assure Safe Use" (ETASU), which the FDA may impose on a drug that has been shown to be effective only if it is associated with a "serious adverse drug experience" (defined as resulting in death, immediate risk of death, inpatient hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly or birth defect).[29,30] In 2017, of the nearly 1,800 FDA-approved prescription drugs and therapeutic biologic active ingredients on the U.S. market, only seventy-three were subject to a REMS—and just forty-three were subject to a REMS with ETASU.[31] Importantly, ETASU are not to be "unduly burdensome on patient access to the drug, considering in particular … patients who have difficulty accessing health care (such as patients in rural

[23] Complaint at 19, Chelius v. Wright, 2017 WL 4401999 (D.Hawai'i). When the complaint was filed in 2017, it named then-Acting Secretary of Department of Health and Human Services Don Wright. Later stages of litigation name Secretary Alex Azar. *Id*.

[24] *Id*. (citing U.S. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RSCH., App. No. 020687Orig1s020, Mifeprex Medical Review(s) (Mar. 29, 2016), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf (last visited Mar. 10, 2021)).

[25] FDA, *Mifepristone Information*, *supra* note 8.

[26] Complaint, Chelius v. Wright, 2017 WL 4401999 (D.Hawai'i).

[27] *Id*.

[28] *Id*.

[29] Complaint at 18-19, Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin., 2020 WL 2771735 (D.Md.).

[30] 21 U.S.C.A. § 355-1.

[31] Complaint at 4, Chelius v. Wright, 2017 WL 4401999 (D.Hawai'i).

or medically underserved areas)."[32] In California, the Medi-Cal Provider Manual mandates that providers adhere to the enumerated FDA REMS in order to bill for a bundled payment reimbursement for MAB.[33] Considering that Medi-Cal covers about half of abortions in California, we know that the Mifeprex REMS with ETASU directly impact many low-income patients across the state.[34] California adults qualify for Medi-Cal if their income is up to 138% of the federal poverty level, or $17,609 in 2020.[35]

The three ETASU assigned to Mifeprex are as follows:

- ETASU A: Clinicians prescribing mifepristone must send a prescriber agreement form to the drug distributor attesting to their clinical abilities, agreeing to comply with certain reporting requirements, and agreeing to comply with other REMS elements.[36]
- ETASU C: Mifepristone may be dispensed only in a hospital, clinic, or medical office—not in retail pharmacies—by or under the supervision of a certified prescriber.[37]
- ETASU D: The prescriber and patient must, in person, review and sign a special Patient Agreement Form containing information regarding the mifepristone.[38]

According to experts, the FDA's decision to place these stringent regulations on Mifeprex was "highly unusual."[39] Nearly twenty years of data provides Mifeprex with a record of up to ninety-nine percent efficacy and exceptional safety.[40] In the first fifteen years of U.S. post-marketing data on Mifeprex, there were seventeen reported associated deaths out of 2.5 million uses—an associated fatality rate of 0.00068%.[41] Further, in 2016 the FDA determined that because adverse events associated with mifepristone are so

[32] 21 U.S.C.A. § 355-1.

[33] *Medi-Cal Provider Manual for abortion (abort)* at 7, CALIF. DEP'T OF HEALTH CARE SERVS. (updated Sept. 16, 2020), available at https://filesacceptttest.medi-cal.ca.gov/pubsdoco/Publications/masters-MTP/Part2/abort.pdf [hereinafter *Medi-Cal Provider Manual*].

[34] Nicole E. Johns, Diana Greene Foster & Ushma D. Upadhyay, *Distance traveled for Medicaid-covered abortion care in California*, 17 BMC HEALTH SERV. RES. 287 (2017) (citing CALIF. DEP'T OF HEALTH CARE SERVS., *Medi-Cal funded induced abortions, 2010*).

[35] *Do You Qualify for Medi-Cal Benefits?*, CALIF. DEP'T OF HEALTH CARE SERVS. (May 5, 2020), https://www.dhcs.ca.gov/services/medi-cal/Pages/DoYouQualifyForMedi-Cal.aspx.

[36] 21 U.S.C.A. § 355-1(f)(3)(A).

[37] 21 U.S.C.A. § 355-1(f)(3)(C).

[38] 21 U.S.C.A. § 355-1(f)(3)(D).

[39] Complaint at 20, Chelius v. Wright, 2017 WL 4401999 (D.Hawai'i).

[40] U.S. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RSCH., App. No. 020687Orig1s020, Mifeprex Medical Review(s) at 23 (Mar. 29, 2016), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf (last visited Mar. 10, 2021) [hereinafter FDA, *Mifeprex Medical Review*].

[41] *Id*. at 82-83.

rare, it was appropriate for the manufacturer to cease reporting adverse events other than death.[42] The FDA has acknowledged that "[t]here is no information that use of Mifeprex and misoprostol caused the 'very small number' of deaths from infection. Rather… [CDC findings suggest] pregnancy itself was the 'critical risk factor' [in] cases of fatal infection."[43] Ironically, given the United States' dismal maternal mortality rate, the associated fatality risk of carrying a pregnancy to term is about fourteen times greater than the risk of using Mifeprex.[44]

By way of comparison, mifepristone-based drug Korlym is often prescribed as treatment for Cushing syndrome, a disease caused by high levels of the hormone cortisol.[45,46] Even though Korlym is taken daily, at home, in higher doses, and with higher rates of adverse events than Mifeprex, Korlym is not subject to a REMS.[47] In a final comparison, the fatality rate associated with phosphodiesterase type five inhibitors for the treatment of erectile dysfunction (e.g., Viagra) is estimated at 0.0026%, roughly four times that of Mifeprex.[48] Yet, prescription Viagra is not subject to a REMS.[49] These statistics, considered in light of brazen and persistent calls by anti-abortion politicians to ban MAB specifically, suggest that the REMS are motivated not by concern for patient safety but by political will.[50]

Provider certification like the kind required by ETASU A is not required for professionals to dispense many other drugs, some of which include "black box" warnings about their risks.[51] Moreover, the prescriber agreement forces abortion providers to self-identify to an entity that is routinely inspected by

[42] Complaint at 35, Chelius v. Wright, 2017 WL 4401999 (D.Hawai'i).

[43] *Id.* at 38. Of the seventeen reported deaths in women who had taken Mifeprex, five involved events unrelated to the medication, such as narcotic overdose or suspected homicide. *Id.*

[44] *Id.* at 3.

[45] FDA, *Mifeprex Medical Review*, *supra* note 40, at 10.

[46] "Cushing syndrome occurs when [a] body is exposed to high levels of the hormone cortisol for a long time." *Cushing Syndrome*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/cushing-syndrome/symptoms-causes/syc-20351310.

[47] FDA, *Mifeprex Medical Review*, *supra* note 40, at 10.

[48] Complaint at 38, Chelius v. Wright, 2017 WL 4401999 (D.Hawai'i).

[49] *Id.* at 35.

[50] William Cummings, *'Pregnancy is not a life-threatening illness': Ted Cruz takes heat in call to ban abortion pill*, USA TODAY (Sept. 3, 2020), https://www.usatoday.com/story/news/politics/2020/09/03/ted-cruz-pregnancy-not-life-threatening-abortion-bill-ban/5700978002/.

[51] A "black box warning" or "boxed warning" appears on a prescription drug's label and is designed to call attention to serious or life-threatening risks. *Consumer Health Information, A Guide to Drug Safety Terms at FDA* at 2, U.S. FOOD & DRUG ADMIN. (Nov. 2012), https://www.fda.gov/downloads/forconsumers/consumerupdates/ucm107976.pdf.

the federal government.[52] Considering some policymakers' politicization of abortion rights and the violence routinely perpetrated against abortion providers, this requirement effectively weeds out clinicians who may be uncomfortable publicly identifying as abortion providers—especially in abortion-hostile regions.[53] With fewer providers willing to stock the medication, there are fewer opportunities for patients to access MAB in places where state-level restrictions already pose significant barriers.

Particularly resonant for the goals of this note, the in-person dispensation requirement (ETASU C) serves no medical purpose. Of the three ETASU assigned to Mifeprex, this requirement is among the rarer ETASU assigned to a drug and provides the biggest barrier to access for patients. Out of more than 20,000 drugs regulated by the FDA—including self-administered injectables, opioids, and other drugs with high potential for danger or abuse— Mifeprex is the only one that patients must receive in person at a hospital, clinic, or medical office, yet may self-administer unsupervised at a location of their choice.[54] Experts agree that the dispensing location has no effect on the safety or efficacy of the medication.[55] As the Mifeprex label makes clear, the medication's effects do not begin until hours after ingestion: "most women will expel the pregnancy within 2 to 24 hours of taking misoprostol [the second drug in the regimen]."[56] This amounts to a total of twenty-six to seventy-two hours *after* taking mifepristone; and for patients in states with mandatory waiting periods for abortion care, this could mean up to four days after the patient first presents to a clinician. It is highly unlikely that a patient will still be under the direct supervision of her certified prescriber if she experiences adverse effects at that time. In short, "there is no relationship between where a woman is standing when she receives the Mifeprex pill and any potential risk of infection or bleeding."[57] There is no

[52] Complaint at 27, Chelius v. Wright, 2017 WL 4401999 (D.Hawai'i) (citing to Letter from SFP, et al., to Stephen Ostroff, M.D., Robert M. Califf, M.D., & Janet Woodcock, M.D. (Feb. 4, 2016)).

[53] *Id.* In 2014, one in five U.S. health care facilities that provide abortions experienced "severe violence" such as blockades, invasions, bombings, arsons, chemical attacks, physical violence, stalking, gunfire, bomb threats, arson threats, or death threats.

[54] Complaint at 3, Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin., 2020 WL 2771735 (D.Md.).

[55] Complaint at 41, Chelius v. Wright, 2017 WL 4401999 (D.Hawai'i).

[56] Mifeprex (Mifepristone) Tablets Label, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (last visited Mar. 13, 2021). Mifeprex labeling is a rigorous part of the FDA approval process. Thanks to persuasion from doctors and professional medical associations—including some plaintiffs in the *Chelius* case—the FDA has made significant updates to the Mifeprex label over time that more accurately communicate its uses.

[57] Complaint at 37, Chelius v. Wright, 2017 WL 4401999 (D.Hawai'i).

evidence-based connection between in-person dispensation and patient safety.

Similarly, regarding ETASU D, there is no data suggesting that a patient's location when signing a form has any effect on the safety or efficacy of the medication—whether she is signing it in the physical presence of a doctor or virtually via a telehealth visit. But more importantly, many clinicians agree that the signing of the Patient Agreement form is altogether duplicative, emotionally draining, and interferes with the patient-physician relationship.[58] Abortion patients already receive extensive counseling under standard informed consent practices, they receive the FDA-regulated Medication Guide for Mifeprex, and they are subject to additional counseling practices that vary across states and individual clinics or hospitals.[59] Adding an additional layer of consultation via a Patient Agreement form is, again, not medically necessary.

Finally, as with any substance regulated by the government, erecting barriers to access cements the risk of desperate patients turning to sketchy sources. While more research is needed to understand the scope of this issue, we know that some patients obtain MAB drugs online from unlicensed foreign sellers.[60] These patients have no clinical supervision, have not undergone a professional screening, and may not understand potential contraindications resulting in true adverse reactions. These conditions set a dangerous stage reminiscent of pre-*Roe* America, when desperate patients resorting to unsafe methods of abortion resulted in an estimated 200 deaths per year.[61]

Physicians and experts across the country, including at least one former FDA administrator, agree that the outdated REMS should be lifted.[62] The American College of Obstetrics and Gynecologists (ACOG), the country's leading group of physicians providing health care for women, has urged removal of the REMS on behalf of its 60,000 members.[63] As of the time of

[58] Telephone Interview with Mary Fjerstad, Clinician, on Nov. 11, 2020 (on file with author).

[59] Complaint at 28-30, Chelius v. Wright, 2017 WL 4401999 (D.Hawai'i).

[60] Gabriella Borter, *U.S. states unsure how to halt online sales of abortion pills amid clinic crackdown*, REUTERS (June 27, 2019), https://www.reuters.com/article/us-usa-abortion-pills/u-s-states-unsure-how-to-halt-online-sales-of-abortion-pills-amid-clinic-crackdown-idUSKCN1TS1AB.

[61] *All Things Considered: What Abortion Was Like In The U.S. Before Roe v. Wade* at 1:46, NPR (May 20, 2019), https://www.npr.org/2019/05/20/725139713/what-abortion-was-like-in-the-u-s-before-roe-v-wade.

[62] Jane E. Henney & Helene D. Gayle, *Time to Reevaluate U.S. Mifepristone Restrictions*, 381 THE NEW ENGLAND J. OF MED. 597, 597-98 (2019).

[63] *Improving Access to Mifepristone for Reproductive Health Indications: Position Statement*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS (June 2018),

this writing, the Biden-Harris Administration has signaled strong support for reproductive rights expansion; however, the president has yet to nominate the FDA commissioner who would ultimately make the call to remove the REMS on mifepristone.[64] A permanent removal of the REMS would not only reduce barriers to access, but in some places would allow for completely remote provision of TeleMAB. This is because while eighteen states explicitly prohibit abortion via telehealth, other states, including California, have no such restrictions.[65] While TeleMAB is still in early days of study, researchers and advocates feel confident in its promise to substantially reduce costs while vastly increasing access. TeleMAB could remove many of the associated costs, stressors, and inconveniences experienced by low-income and rural abortion patients, such as traveling to a clinic, taking time off work, securing childcare, and undergoing anesthesia.[66]

B. The COVID-19 Public Health Emergency and MAB

When the seriousness of the COVID-19 pandemic became evident to the public in early 2020, the federal government and all fifty states declared some level of public health emergency.[67] As travel restrictions, social distancing protocols, and decreased capacity at hospitals and clinics vastly hindered health care delivery, an obvious means of expanding access to care was through telehealth. Even as the Trump Administration downplayed the seriousness of the pandemic, the Department of Health and Human Services took historic action to expand telehealth services by relaxing federal privacy

https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications.

[64] *See* Sarah McCammon, *Biden Administration Prepares To Overturn Trump Abortion Rule*, NPR (Jan. 21, 2021), https://www.npr.org/sections/president-biden-takes-office/2021/01/21/959170860/biden-administration-prepares-to-overturn-trump-abortion-rule; Laurie McGinley, *Biden's delay on naming FDA chief perturbs some experts*, WASH. POST (Feb. 11, 2021), https://www.washingtonpost.com/health/2021/02/11/biden-fda-appointment-covid/.

[65] Melissa Jeltsen, *Coronavirus Is Endangering Abortion Access. Telemedicine Could Solve it.*, HUFF. POST (Mar. 20, 2020), https://www.huffpost.com/entry/medication-abortion-telemedicine_n_5e74ec23c5b6eab779472982.

[66] *See generally TelAbortion.org*, GYNUITY HEALTH PROJECTS, https://telabortion.org/ (last visited Mar. 13, 2021).

[67] *Status of State COVID-19 Emergency Orders*, NAT'L GOVERNORS ASS'N https://www.nga.org/state-covid-19-emergency-orders/ (visited Jan. 23, 2021); Samuel Wonacott, *All 50 states have active declared emergencies related to the coronavirus pandemic*, BALLOTPEDIA NEWS (July 29, 2020, 3:47 PM), https://news.ballotpedia.org/2020/07/29/all-50-states-have-active-declared-emergencies-related-to-the-coronavirus-pandemic/.

laws.[68] In an effort to encourage the use of telehealth services, on April 3, 2020, California Governor Gavin Newsom issued an executive order removing several obstacles to telehealth provision, including the relaxing of requirements around signing telehealth consent forms.[69]

Meanwhile, clinicians and advocates witnessed growing challenges for those seeking health care across the board: local lockdown mandates compounded traditional barriers like financial strain and finding childcare; showing up to facilities for in-person care exacerbated the risk of COVID-19 exposure; and, health risks associated with delays in care grew more dire by the day. Even as at least eleven states seized the opportunity to put more restrictions on abortion or ban it outright, advocates took critical steps to ensure that abortion care would remain safe and accessible.[70] In March 2020, ACOG issued a statement acknowledging that dating a pregnancy based on a patient's last menstrual period (LMP) without ultrasound was acceptable for MAB.[71] In April 2020, leading physicians, researchers, and professional organizations developed a "no-touch" or "no-test" protocol deemed not only acceptable for MAB provision, but safe, effective, and commensurate with the traditional standard of care.[72]

In May 2020, the American Civil Liberties Union (ACLU) filed suit on behalf of ACOG to lift the FDA's REMS requirements on mifepristone.[73] Specifically, the ACLU alleged that the FDA's continued enforcement of the requirements to pick up the medication and sign specific forms in person unnecessarily exposed patients and clinicians to heightened risk of exposure to COVID-19 for no medical purpose, and that the in-person requirements put their health and lives at risk.[74] The plaintiffs also pointed out that the FDA relaxed in-person requirements for other highly regulated drugs during the pandemic, "to afford clinicians discretion to provide appropriate medical

[68] *Secretary Azar Announces Historic Expansion of Telehealth Access to Combat COVID-19*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Mar. 17, 2020), https://www.hhs.gov/about/news/2020/03/17/secretary-azar-announces-historic-expansion-of-telehealth-access-to-combat-covid-19.html.

[69] Calif. Exec. Order No. N-43-20 (Apr. 3, 2020), https://www.gov.ca.gov/wp-content/uploads/2020/04/4.3.20-EO- N-43-20-text.pdf.

[70] These bans did not survive legal challenges but created confusion and fear among patients.

[71] *COVID-19 FAQs for Obstetrician–Gynecologists, Gynecology*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, https://www.acog.org/clinical-information/physician-faqs/covid19-faqs-for-ob-gyns-gynecology (last visited Mar. 13, 2021).

[72] Elizabeth G. Raymond et al., *Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond*, 101 CONTRACEPTION 361, 361-66 (2020).

[73] Complaint, Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin., 472 F.Supp.3d 183 (D.Md. 2020), No. TDC-20-1320, 2020 WL 2771735.

[74] *Id.* at 18-19.

care under these emergency circumstances," but not mifepristone.[75] In a July 2020 decision, the U.S. District Court for the District of Maryland ruled for ACOG in *American College of Obstetricians and Gynecologists v. FDA*, representing a huge win for access.[76] The court enjoined the FDA's in-person requirements for prescribing mifepristone for the duration of the public health emergency.[77]

The federal injunction immediately impacted MAB provision across the country in critical ways. Most importantly, the injunction allowed mifepristone to be dispensed by mail or delivery service unless otherwise restricted by state law.[78] Though mifepristone still had to be prescribed by or under the supervision of a certified health care provider as defined in the REMS, mail-order pharmacies could serve as intermediaries, sparing patients the in-person trips to their prescribing health care facility.[79] Additionally, patients were permitted to physically or electronically sign the Patient Agreement form during a telehealth appointment and return the form electronically or by mail; alternatively, a patient could give verbal consent to the terms of the form during a telehealth session.[80] The injunction was set to apply for thirty days past the end of the national public health emergency.[81]

If there is a silver lining to the COVID-19 pandemic, it is that under the injunction providers, researchers, and activists were able to administer MAB with significant barriers removed. But this small win was short-lived. After multiple unsuccessful attempts to stay the injunction, the Trump Administration finally prevailed in a last-ditch appeal: on January 12, 2021, in its first abortion-related decision since Justice Amy Coney-Barrett's confirmation, the United States Supreme Court re-imposed the in-person dispensation and signature requirements.[82] In a short concurrence, Chief Justice John Roberts opined that the courts should defer to "politically accountable entities" on decisions related to pandemic governance.[83] In a sharp dissent rebuking the Court's decision, Justice Sonia Sotomayor pointed out that a stay of a district court's injunction has in the past been viewed as

[75] Complaint at 27, Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin., 472 F.Supp.3d 183 (D.Md. 2020), No. TDC-20-1320, 2020 WL 2771735.

[76] Order Clarifying July 13 Memorandum Opinion, Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin., No. TDC-20-1320, 2020 WL 8167535 (D. Md. Aug. 19, 2020).

[77] *Id*.

[78] *Id*.

[79] *Id*.

[80] *Id.*

[81] *Id*.

[82] Food & Drug Admin. v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578 (2021).

[83] *Id.* at 579.

"extraordinary" relief.[84] In addition to highlighting the fact that the pandemic has only worsened in the months since the injunction was first ordered, Justice Sotomayor called out the FDA's inconsistent and flawed approach to decision-making during the pandemic: "Government policy now permits patients to receive prescriptions for powerful opioids without leaving home, yet still requires women to travel to a doctor's office to pick up mifepristone, only to turn around, go home, and ingest it without supervision."[85] Abortion advocates, including ACOG, have also derided the Court's decision.[86]

What happens next? Several advocacy organizations are urging the Biden Administration to suspend enforcement of the in-person requirements for the duration of the pandemic.[87] This would effectively reverse course on the Supreme Court's decision. In California, a suspension of enforcement would allow patients to continue to access MAB via telehealth and mail-order pharmacy.

C. Recommendation: California Should Foster Analysis of MAB Data Collected While In-Person Requirements Were Lifted

For the brief period of July through December 2020, TeleMAB was a reality for patients across California. Though it is still too soon to know how many patients utilized these services, it is possible that there is significant data to inform the State's planning for MAB expansion, especially if the REMS are permanently lifted. But regardless of the Administration's actions, many advocates feel as though "the cat is out of the bag" and that TeleMAB will only continue to expand.[88] In preparation for that reality, the State of California has a unique opportunity to understand outcomes associated with no-touch MAB and TeleMAB: the State should launch an effort to centralize and analyze data surrounding MAB provision while the REMS were lifted.

This would ideally be a repository where providers can share comprehensive notes and data – clinic information (including geography and

[84] *Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. at 579 (Sotomayor, J., dissenting).

[85] *Id*.

[86] *See, e.g.*, ACOG Action (@ACOGAction), TWITTER (Jan. 12, 2021, 5:16 PM), https://twitter.com/ACOGAction/status/1349148168877969411?s=20.

[87] Georgeanne M. Usova, *The Supreme Court Let the Trump Administration Endanger Abortion Patients During a Pandemic. The Biden-Harris Administration Can Fix It Right Away.*, ACLU (Jan. 14, 2021), https://www.aclu.org/news/reproductive-freedom/the-supreme-court-let-the-trump-administration-endanger-abortion-patients-during-a-pandemic-the-biden-harris-administration-can-fix-it-right-away/.

[88] Susan Rinkunas, *A Bitter Pill*, MARIE CLAIRE (Jan. 13, 2021), https://www.marieclaire.com/politics/a35203155/pandemic-abortion-telemedicine.

community demographics), patient demographics (age, race, income level, language preferences), insurance information (particularly around Medi-Cal reimbursement), health and safety outcomes, follow-up information, anecdotal evidence, testimonials from patients and providers, challenges and successes with different technology platforms, experiences with mail-order infrastructure, and more. Several private and non-profit entities already collect such data points, but there is no centralized effort across the state to focus explicitly on COVID-19-era outcomes.[89] After collection, the State can assess the data and evaluate TeleMAB models based on specific factors such as:[90]

- Accessibility of services and appointments relative to patient needs
- Ready supply of MAB relative to patient needs
- Use of technology platforms and accommodations made for patients with disabilities, unstable internet connections, and limited devices
- Affordability of services
- Provider comfort level and satisfaction with remote counseling, prescription, and dispensation of MAB
- Patient comfort level and satisfaction with remote counseling, prescription, dispensation, and abortion procedure
- Medical outcomes and adverse drug experiences

This information, combined with data from the Department of Health Care Services (DHCS) around changes in Medi-Cal reimbursements discussed in the next section of this note, will empower California to contribute to ongoing research on the promise of TeleMAB—with special attention to low-income patients. After analysis, the State can share its findings with those working to expand access at the federal and state levels, bolstering the case for permanently removing the REMS restrictions and building policy infrastructure for widely accessible TeleMAB. Months' worth of insight can inform policy, guide providers and pharmacies, and codify processes for a smooth transition into the future of reproductive health care.

Opponents would argue that the State has competing priorities during the COVID-19 public health emergency, and that California has limited resources to direct at a time when the health and economic livelihoods of its residents are at stake. This is a valid argument: data shows that California

[89] Some of these institutions are cited in this note, including Planned Parenthood, Kaiser Family Foundation, Ibis Reproductive Health, Guttmacher Institute, and Gynuity Health Projects, in addition to researchers at various academic research centers like the University of California, San Francisco's Bixby Center for Global Reproductive Health.

[90] *Telehealth for Medication Abortion Delivery Models*, IBIS REPRODUCTIVE HEALTH (Oct. 2019) (these criteria suggestions are based off criteria developed by Ibis Reproductive Health's study of telehealth abortion models).

experienced massive spikes in infections and death from COVID-19—not to mention the devastating impacts to its economy and the health and safety of our most vulnerable residents.[91] The death rate for Latino people is twenty-one percent higher than the statewide average; the death rate for Black people is six percent higher than statewide; the case rate for Pacific Islanders is thirty-one percent higher than statewide; and the case rate for communities with median income under $40,000 is thirty-eight percent higher than statewide.[92] A feasible alternative solution would be for the state to outsource or corral organizations across the state that already collect similar data. This solution would involve the aggregation and streamlining of that information at the tail end of data collection. In 2016, nonprofit organization Gynuity Health Projects launched a study on TeleMAB with the goal of proving its safety and efficacy.[93] Now running in thirteen states and the District of Columbia, the study tracks pregnant patients who receive virtual counseling with an abortion provider, go to any local facility to undergo any necessary testing, and then receive mifepristone and misoprostol by mail.[94] The State could cut down on resource expenses by contracting with an organization like Gynuity, which receives funding from a combination of research institutions, foundations, and agencies.[95]

A likely obstacle to implementation would be hesitancy on the part of providers to submit information about abortion provision. As previously discussed, given the political nature of abortion and the prevalence of anti-abortion violence, providers are often wary of submitting any identifying information about themselves, their patients, and their practices, due to privacy, confidentiality, and security concerns.[96] One solution to mitigate these concerns might be for the State to engage trusted, credible, and respected physicians and experts to encourage provider participation. The reproductive rights advocacy community in California is strong and tight-knit; it is plausible that having a few key people on board early in the process may create momentum for participation. Such a data collection program

[91] *Tracking COVID-19 in California*, CA.GOV, https://covid19.ca.gov/state-dashboard/ (last visited Mar. 13, 2021). At the time of this writing, California has 3,523,563 confirmed cases of COVID-19, resulting in 55,095 deaths.

[92] *California's Commitment to Health Equity*, CA.GOV, https://covid19.ca.gov/equity/ (last visited Mar. 16, 2021).

[93] *See For Providers & Allies*, GYNUITY HEALTH PROJECTS, https://telabortion.org/about/for-providers (last visited Mar. 13, 2021).

[94] *TelAbortion*, GYNUITY HEALTH PROJECTS, https://telabortion.org/_/assets/TelAbortion-One-pager-May-2020.pdf (last visited Mar. 13, 2021).

[95] *Donors*, GYNUITY HEALTH PROJECTS, https://gynuity.org/donors (last visited Mar. 13, 2021).

[96] Telephone Interview with Lisa Matsubara, General Counsel and Vice President of Policy, Planned Parenthood Affiliates of California, on Nov. 25, 2020 (on file with author).

would necessitate the strictest security, and all identifying information about providers and patients would be stripped upon submission.

III. INCREASING MEDICATION ABORTION ACCESS UNDER MEDI-CAL

Public funding represents a significant obstacle for people seeking health care across the country. This is especially true for abortion care, even in California. Despite the State's express commitment to reproductive rights,[97] current requirements for Medi-Cal reimbursement can make MAB inaccessible. This section discusses funding restrictions, how Medi-Cal patients are affected, and why lifting the dual-ultrasound requirement is a viable solution.

A. Federal Abortion Funding Restrictions

A patient's right to obtain any method of abortion in the United States is famously protected by the U.S. Constitution's Fourteenth Amendment under *Roe v. Wade*.[98] But for millions of people of reproductive age across the country, access to abortion is difficult. For low-income patients, patients in abortion-hostile states, and patients in rural areas in particular, accessing abortion care poses significant challenges.[99] This is largely due to gaps in funding and relentless efforts by state legislators to shut down abortion clinics. As of March 2020, there were twenty-seven "abortion deserts" in the United States, defined as regions where women have to travel more than 100 miles to access an abortion.[100] Six states are down to just one clinic.[101] Depending on location, gestation, and method, early-term abortion services range in cost from $300 to about $1,700 and between $300 and $800 for MAB.[102,103] This does not include associated costs of transportation, missed work wages, childcare, and lodging for patients who are forced to travel far

[97] *E.g.*, California Proclamation on Reproductive Freedom (May 31, 2019), available at https://www.gov.ca.gov/wp-content/uploads/2019/05/Proclamation-on-Reproductive-Freedom.pdf.

[98] Roe v. Wade, 410 U.S. 113 (1973).

[99] *Although Many U.S. Women of Reproductive Age Live Close to an Abortion Clinic, A Substantial Minority Would Need to Travel Far to Access Services*, GUTTMACHER INST. (Oct. 3, 2017), https://www.guttmacher.org/news-release/2017/although-many-us-women-reproductive-age-live-close-abortion-clinic-substantial.

[100] Jeltsen, *supra* note 65.

[101] *Id.*

[102] Charlotte Cowles, *How Much Does an Abortion Cost? Learn the Facts.*, THE CUT (Nov. 20, 2018), https://www.thecut.com/2018/11/how-much-does-an-abortion-cost.html.

[103] *How Much Does the Abortion Pill Cost?*, CARAFEM, https://carafem.org/how-much-does-the-abortion-pill-cost/ (last visited Feb. 27, 2021).

distances to clinics and must observe state-imposed waiting periods between counseling and procedure.[104]

Just three years after the *Roe* decision enshrined the Constitutional right to choose an abortion, Congress enacted the Hyde Amendment—a major financial barrier to accessing abortion care.[105] The Hyde Amendment bans federal Medicaid funding for abortion services, except in cases where continuing the pregnancy will endanger the life of the patient or when the pregnancy results from rape or incest.[106] It also restricts abortion funding under the Indian Health Service, Medicare, and the Children's Health Insurance Program (CHIP).[107] An estimated nineteen percent of women of reproductive age in the United States rely on Medicaid.[108] The Hyde Amendment ensures that those patients pay out-of-pocket for abortion care. The policy has withstood legal challenges, most famously in the 1980 case of *Harris v. McRae*, which holds that states are not obligated to pay for abortion care and that Hyde does not violate the Fifth Amendment nor the Establishment Clause of the First Amendment.[109] Though President Biden has voiced support for ending the Hyde Amendment, its future remains unclear as a majority of Congressional Republicans continue to embrace the restriction.[110]

A 2019 regulation promulgated by the Department of Health and Human Services represents a more recent effort to limit federal funding for abortion.[111] Known among abortion care advocates as the "domestic gag rule," the rule effectively forces programs that rely largely on federal Title X funding to choose between receiving funds and providing abortion services.[112] Consequently, many programs, including Planned Parenthood—

[104] Cowles, *supra* note 102; *State Laws and Policies: Counseling and Waiting Periods for Abortion*, GUTTMACHER INST. (updated Mar. 1, 2021), https://www.guttmacher.org/state-policy/explore/counseling-and-waiting-periods-abortion.

[105] *See* Alina Salganicoff, Laurie Sobel & Amrutha Ramaswamy, *The Hyde Amendment and Coverage for Abortion Services*, KAISER FAM. FOUND. (Jan. 2020), http://files.kff.org/attachment/Issue-Brief-The-Hyde-Amendment-and-Coverage-for-Abortion-Services; Hyde Amendment, Pub. L. No. 94-439 § 209, 90 Stat. 1418, 1434 (1976).

[106] *Id.*

[107] *Id.*

[108] *Id.* at 2-3.

[109] Harris v. McRae, 448 U.S. 297, 326 (1980).

[110] Juliegrace Brufke, *House Republicans vow not to support spending bills that repeal Hyde Amendment*, THE HILL (Jan. 26, 2021, 11:26 AM), https://thehill.com/homenews/house/535863-house-republicans-vow-not-to-support-spending-bills-that-repeal-hyde-amendment.

[111] Ruth Dawson, *Trump Administration's Domestic Gag Rule Has Slashed the Title X Network's Capacity by Half*, GUTTMACHER INST. (Feb. 5, 2020), https://www.guttmacher.org/article/2020/02/trump-administrations-domestic-gag-rule-has-slashed-title-x-networks-capacity-half.

[112] *Id.*

the largest network of family planning provision for low-income people in country—have withdrawn from the Title X program altogether.[113] Before the domestic gag rule was instated, around 4,000 clinics received Title X funding, serving approximately four million patients annually.[114] It is estimated that the rule has reduced the Title X network's capacity by forty-six percent nationwide, and by much more in many states.[115] California is one of nine states in which Planned Parenthood served at least fifty percent of contraceptive clients served at Title X–funded centers before the rule was implemented.[116]

Within days of his inauguration, President Biden took steps to "undo the damage" of these Trump Administration policies.[117] Most notably, the president signed an executive order rescinding the harmful global gag rule, which prevented U.S.-funded organizations overseas from providing or counseling for abortion services.[118] During his campaign, the president vowed to similarly reverse the domestic gag rule; as of the time of this writing, the Administration has taken steps to "consider" revocation but the rule is still in effect.[119]

B. The Myth of California as a Haven State

California affords greater protection of a patient's right to choose an abortion than does the U.S. Constitution. In 1969, California recognized the right of procreative choice under the State Constitution.[120] In 1972, Californians amended the State Constitution to include an explicit protection for privacy, which has been interpreted as protecting the right to choose

[113] David Crary & Ricardo Alonso-Zaldivar, *Planned Parenthood leaves federal family planning program*, ASSOCIATED PRESS (Aug. 19, 2019), https://apnews.com/article/9e62021bcde04e69aa2ffc2e70a60f8f; *see also The Irreplaceable Role of Planned Parenthood Health Centers*, PLANNED PARENTHOOD (Jan. 2019), https://www.plannedparenthood.org/uploads/filer_public/33/63/3363814b-938e-4ad5-87d2-57ee98790766/190117-irreplaceable-role-pp-v01.pdf.

[114] Dawson, *supra* note 111.

[115] *Id.*

[116] The State of California failed in its effort to enjoin the rule in *California ex. rel. Becerra v. Azar*, 950 F.3d 1067 (9th Cir. 2020).

[117] Ema O'Connor, *Biden Just Repealed One of Trump's Major Anti-Abortion Policies*, BUZZFEED NEWS (Jan. 28, 2021), https://www.buzzfeednews.com/article/emaoconnor/biden-executive-order-abortion-global-gag-rule-trump.

[118] *Id.*

[119] *Id.*

[120] People v. Belous, 458 P.2d 194, 199 (Cal. 1969) ("[t]he fundamental right of the woman to choose whether to bear children follows from the Supreme Court's and this court's repeated acknowledgement of a 'right of privacy' or 'liberty' in matters related to marriage, family, and sex.").

abortion.[121] In 2002, the State legislature codified a statute guaranteeing that "every woman has the fundamental right to choose to bear a child or to choose and to obtain an abortion."[122] And in 2019, Governor Newsom issued an executive "Proclamation on Reproductive Freedom"—a symbolic commitment to the recognition and expansion of reproductive rights including abortion.[123] California is one of sixteen states to use its own Medicaid dollars to cover abortion for low-income women for any reason.[124] In addition, the State's Family Planning Access Care Treatment (PACT) program provides coverage for family planning services to uninsured women up to two-hundred percent of the federal poverty level.[125] All told, an estimated twenty-six percent of California women of reproductive age rely on Medicaid, and Medi-Cal covers about half of California abortions.[126,127]

This supportive policy environment, plus a massive expansion of Medi-Cal under the Affordable Care Act, gives California the reputation of a haven state for abortion provision. But the State is not immune to disparities in access, particularly when it comes to low-income patients. The combination of a limited number of providers in rural areas, barriers to patient enrollment, and low Medi-Cal reimbursement rates significantly deter Medi-Cal-eligible abortion patients from getting care. About forty percent of counties in California do not have an abortion provider, and a 2011 study of low-income women relying on Medicaid found that twelve percent traveled fifty-plus

[121] CAL. CONST. art. I, § 1; Comm. to Defend Reproductive Rights v. Myers, 625 P.2d 779, 798 (Cal. 1981).

[122] CAL. HEALTH & SAFETY CODE § 123462.

[123] California Proclamation on Reproductive Freedom (May 31, 2019), available at https://www.gov.ca.gov/wp-content/uploads/2019/05/Proclamation-on-Reproductive-Freedom.pdf.

[124] Alina Salganicoff, Laurie Sobel & Amrutha Ramaswamy, *Coverage for Abortion Services in Medicaid, Marketplace Plans and Private Plans*, KAISER FAM. FOUND. (June 24, 2019), https://www.kff.org/womens-health-policy/issue-brief/coverage-for-abortion-services-in-medicaid-marketplace-plans-and-private-plans/ [hereinafter KAISER, *Coverage*]; *State Funding of Abortion Under Medicaid*, GUTTMACHER INST. (Feb. 1, 2021), https://www.guttmacher.org/state-policy/explore/state-funding-abortion-under-medicaid.

[125] Family PACT, however, does not cover abortion services. *Beyond the Numbers: Access to Reproductive Health Care for Low-Income Women in Five Communities*, KAISER FAM. FOUND. (Nov. 14, 2019), https://www.kff.org/womens-health-policy/report/beyond-the-numbers-access-to-reproductive-health-care-for-low-income-women-in-five-communities/ [hereinafter KAISER, *Beyond the Numbers*].

[126] KAISER, *Coverage*, *supra* note 124.

[127] Nicole E. Johns, Diana Greene Foster & Ushma D. Upadhyay, *Distance traveled for Medicaid-covered abortion care in California*, 17 BMC HEALTH SERV. RES. 287 (2017) (citing CALIF. DEP'T OF HEALTH CARE SERVS., *Medi-Cal funded induced abortions, 2010*).

miles to obtain a publicly funded abortion.[128,129]

A Kaiser Family Foundation case study of Tulare County, located in the central region, illustrates the issue of access.[130] One of the poorest counties in California, Tulare has a host of challenges present in regions across the State: extreme poverty, prevalence of domestic violence, and a significant population of undocumented immigrants who face language barriers and/or do not seek services out of fear of deportation.[131] Women in Tulare County cited transportation, cost, stigma, and "fear of family members finding out" as major hurdles to accessing abortion.[132] Those who do seek abortion care must travel more than fifty miles to the nearest city of Fresno.[133] Study participants said that the community is conservative largely due to Roman Catholic influence in the sixty-five percent Hispanic population, which leads to resistance to abortion from both providers and patients.[134] Considering Tulare, it is no surprise that patients who rely on Medi-Cal across the State have difficulty finding a provider where they live.

Further, misconceptions and misinformation about Medi-Cal eligibility also affect enrollment in the Medi-Cal program.[135] According to data and anecdotal evidence, patients are sometimes incorrectly told that they need to submit certain forms or information, such as citizenship documents, in order to qualify for coverage.[136] (In reality, citizenship documents are not required.[137]) Again, these misconceptions lead to delayed care, pregnancy-related complications, and carrying unwanted pregnancies to term.[138]

Finally, California's low Medi-Cal reimbursement rates are an obstacle to MAB access. In a multi-state study of barriers to Medicaid acceptance for all methods of abortion, providers cited low reimbursement rates as the

[128] Rachel K. Jones, Elizabeth Witwer & Jenna Jerman, *Abortion Incidence and Service Availability in the United States, 2017*, GUTTMACHER INST. (Sept. 2019), https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017.

[129] Nicole E. Johns, Diana Greene Foster & Ushma D. Upadhyay, *Distance traveled for Medicaid-covered abortion care in California*, 17 BMC HEALTH SERV. RES. 287 (2017).

[130] KAISER, *Beyond the Numbers*, *supra* note 125.

[131] *Id.*

[132] *Id.*

[133] *Id.*

[134] *Id.*

[135] *Barriers to abortion care in California: Highlighting challenges of Medi-Cal Coverage*, ACCESS WOMEN'S HEALTH JUST., IBIS REPRODUCTIVE HEALTH & ALL ABOVE ALL (Sept. 2016), https://ibisreproductivehealth.org/sites/default/files/files/publications/Brief%20MediCal%20coverage.pdf.

[136] *Id.*

[137] *Id.*

[138] *Id.*

primary barrier.[139] While reimbursement rates and costs of services vary, California has one of the lowest average Medicaid reimbursement rates for physicians in the country.[140] This was exacerbated in 2015 with the passage of AB 97, which enacted a ten percent reduction in reimbursement rates for most fee-for-service Medi-Cal providers.[141] Low reimbursement rates for abortion services can result in steep out-of-pocket costs for patients; fewer providers who accept federal insurance coverage due to lack of reimbursement or process hassles that outweigh the benefits of receiving such low payments; and, clinic closures or reductions in staff due to significant losses on un-reimbursed services.[142]

When seeking Medi-Cal reimbursement specifically for MAB, providers receive a bundled payment for services rendered over a fourteen-to-eighteen-day period and include all office visits, pelvic ultrasounds, laboratory studies, urine pregnancy tests, and patient counseling.[143] One of the costliest pieces of the bundled payment requirements is the pelvic ultrasound. To be eligible for reimbursement, MAB patients in California are required to receive two in-office ultrasounds: the first to determine gestational age of the pregnancy before MAB, and the second, performed after the pill regimen, to ensure termination is complete.[144] The cost of a pregnancy ultrasound typically ranges from $200 to $300 but can be significantly more (the Healthcare Bluebook estimates a "fair" price at $225, though this does not correspond to reimbursement rates for ultrasounds in the in the Medi-Cal fee schedule).[145] According to data from DHCS, in 2014 the average reimbursement rate for fee-for-service, Medi-Cal-funded MAB provision service was $561.[146] Thus,

[139] Amanda Dennis & Kelly Blanchard, *Abortion Providers' Experiences with Medicaid Abortion Coverage Policies: A Qualitative Multistate Study*, 48 HEALTH SERV. RES. 1, 236-52 (2013).

[140] *HHS Administrative Complaint: Inadequate Access to Health Care Violates Latino Civil Rights in California's Medi-Cal Program*, NAT'L HEALTH LAW PROGRAM (Dec. 15, 2015), https://healthlaw.org/resource/hhs-administrative-complaint-inadequate-access-to-health-care-violates-latino-civil-rights/.

[141] *Assembly Bill 97 Ten Percent Pharmacy Payment Reductions*, CALIF. DEP'T OF HEALTH CARE SERVS., https://www.dhcs.ca.gov/provgovpart/pharmacy/Pages/AB97Main.aspx (last modified Sept. 10, 2019, 2:41 PM).

[142] Dennis & Blanchard, *supra* note 139.

[143] *Medi-Cal Provider Manual*, *supra* note 33.

[144] *Id.*

[145] Ruthie Dean, *Expecting? How Much Does an Ultrasound Cost?*, BERNARD BENEFITS (Oct. 14, 2020), https://blog.bernardbenefits.com/expecting-how-much-does-an-ultrasound-cost.

[146] Reimbursement for early pregnancy surgical abortions in 2014 averaged $438. This price differential can be attributed to the costs of pills and to the two-ultrasound requirement for MAB. CALIF. DEP'T OF HEALTH CARE SERVS., RSCH. & ANALYTIC STUDIES DIV., *Medi-Cal-Funded Induced Abortions, 2014* (Oct. 2016),

after covering costs of the ultrasounds, that leaves just a little over $100 to cover the cost of pills, pregnancy and lab tests, plus all remaining staff, office, and administrative costs.

Additionally, it is not uncommon for MAB patients to skip the follow-up appointment and the second ultrasound for logistical or personal reasons, including the inability to take off work, lack of childcare, and the emotional stress of returning to a clinic.[147] In these instances, which are uniquely out of providers' control, providers must use a modifier on their billing that drops reimbursement down by almost fifty percent—a sizable decrease in reimbursement despite the fact that all other costs of provision remain the same.[148] Thus, for many safety-net providers who primarily serve low-income patients, the significant decrease in the reimbursement rate brought about by the modifier makes it is financially difficult to accept Medi-Cal insurance for MAB.

C. Recommendation: California Should Eliminate Pelvic Ultrasounds from MAB Medi-Cal Reimbursement Requirements

Following the July 2020 federal injunction on the FDA REMS for mifepristone, DHCS issued a directive temporarily relaxing requirements for MAB reimbursement under Medi-Cal.[149] DHCS lifted both enforcement of the FDA's in-person requirements *and* the ultrasound requirement from the bundled payment option coded as S0191:

> Providers who bill using HCPCS code S0191 to prescribe mifepristone to end early pregnancies, may provide medically necessary services *without* an in-person visit or signature … Further, DHCS is revising the Abortion (abort) section of the Provider Manual to ensure *flexibilities exist* for providing medically necessary abortion services during the COVID-19 public health emergency and to remove requirements for a Medicare denial for certain abortion services.[150]

https://www.dhcs.ca.gov/dataandstats/statistics/Documents/Medi-Cal-Funded-Abortions-2014.pdf.

[147] Matsubara, *supra* note 96.

[148] *Id.*

[149] *Important News about Women's Health Services*, CALIF. DEP'T OF HEALTH CARE SERVS. (July 29, 2020), https://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_30339_77.aspx.

[150] *Id.* (emphases added).

Permanently eliminating the requirements for ultrasounds for Medi-Cal reimbursement, and rather allowing providers the flexibilities to provide appropriate MAB care based on patient needs and desires, would be a huge win for providers and patients. Not only is the dual ultrasound requirement costly, but it is not medically necessary for patient safety and procedural efficacy.[151]

The three primary goals of a clinical evaluation *before* MAB are to confirm that the gestational age is within accepted limits for safe and effective outpatient treatment, to identify ectopic pregnancy, and to establish that the patient has no contraindications to mifepristone or misoprostol.[152] Historically, an ultrasound is used during clinical evaluation because it was thought to be the best way to determine gestational age of a pregnancy—but it is not the only way to do so: as previously discussed, a no-touch protocol utilizing patient-reported information about last menstrual period (LMP) can help clinicians date gestational age of a pregnancy to an extremely high degree of accuracy.[153] In fact, a prospective study conducted in 2015-2016 in the United States, Mexico, and Moldova provided 406 medication abortions without ultrasound or pelvic examination, and no reported serious adverse events were connected to these omissions.[154] The National Abortion Federation's clinical policy guidelines state that "the use of ultrasound is not a requirement for the provision of first-trimester abortion care"; rather, "use of ultrasound *may inform* clinical decision-making."[155] The FDA does not require ultrasounds as part of the REMS for mifepristone. In fact, the Medication Guide for Mifeprex does not require an ultrasound but says that a provider "may do a clinical examination, an ultrasound examination, or other testing to determine how far along [the patient is] in pregnancy."[156]

The second primary goal of the traditional clinical evaluation before MAB is to identify ectopic pregnancy, a serious condition that occurs when a fertilized egg attaches itself not to the uterus but to a fallopian tube, abdominal cavity, or cervix.[157] Similar to LMP dating, ectopic pregnancies

[151] Raymond et al., *supra* note 72.

[152] *Id*.

[153] Hillary Bracken et al., *Alternatives to routine ultrasound for eligibility assessment prior to early termination of pregnancy with mifepristone–misoprostol*., 118 BJOG 17, 17-23 (2011).

[154] For more than 15 years, international organizations have provided tens of thousands of patients with MAB medications by mail, after screening them only by history. Raymond et al., *supra* note 72.

[155] *2020 Clinical Policy Guidelines for Abortion Care*, NAT'L ABORTION FED'N, https://5aa1b2xfmfh2e2mk03kk8rsx-wpengine.netdna-ssl.com/wp-content/uploads/2020_CPGs.pdf (last visited Feb. 28, 2021) (emphasis added).

[156] *Medication Guide: Mifeprex*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/72923/download (last visited Feb. 28, 2021).

[157] Raymond et al., *supra* note 72.

can be identified through patient-reported information regarding recent vaginal bleeding, pelvic pain or cramping, medical history of pelvic inflammatory disease, or presence of an intrauterine device at conception.[158] While it must be noted that many patients with ectopic pregnancies will exhibit no risk factors, data suggests that the incidence of ectopic pregnancy among patients seeking MAB is less than one percent.[159] Further, the condition can be determined post-MAB through other means like take-home pregnancy testing.[160]

In terms of the third goal of identifying contraindications to the medication, clinicians can use specific questions about medical history and symptoms, typical of routine medication screening, to determine whether a patient is at risk before prescribing.[161]

The follow-up ultrasound requirement *after* MAB is similarly medically unnecessary. The primary goals of the follow-up are to confirm termination of pregnancy, to detect ectopic pregnancies that were previously undiagnosed, and to identify any complications in need of treatment.[162] Patient-reported information about symptoms can be used in conjunction with high-sensitivity pregnancy tests to accomplish these goals, bypassing the need for an ultrasound.[163] (For example, a pregnancy test showing positive post-MAB could suggest presence of an ectopic pregnancy.) Moreover, as previously mentioned, patients are often "lost to follow-up," i.e. they do not present in-office after completing the pill regimen.[164] ACOG's most recent guidelines state that routine in-person follow-ups with an ultrasound are not necessary after an uncomplicated medication abortion.[165] Some clinicians have even offered patients the option to conduct a follow-up appointment by telephone or video as a more convenient and less emotionally taxing alternative to presenting in-office.[166]

A relaxation of the ultrasound requirement could catalyze a domino effect of positive change. Once data from California MAB providers using no-touch protocols is analyzed, it will likely underscore the conclusion that

[158] Raymond et al., *supra* note 72.

[159] *Id*.

[160] *Id*.

[161] *Id*.

[162] *Id*.

[163] *Id*.

[164] *See, e.g*., *Medication Abortion Up to 70 Days Gestation*, ACOG Practice Bulletin (Oct. 2020), https://www.acog.org/-/media/project/acog/acogorg/clinical/files/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-gestation.pdf.

[165] *Id*.

[166] A study found that offering alternative follow-up options to in-person visits, such as telephone or video conferences, may decrease the proportion of women who are lost to follow-ups. Melissa J. Chen et al., *Comparing office and telephone follow-up after medical abortion*, 94 CONTRACEPTION 122, 122-26 (2016).

ultrasounds are not necessary to ensure safe and effective MAB provision. This could reinforce the case for permanent elimination of the ultrasound requirements for Medi-Cal reimbursement, leading to higher reimbursements for MAB, an increase in the number and geographic distribution of providers accepting Medi-Cal for MAB, and broadened access for Californians who need it most—those who rely on Medi-Cal and those who live in areas far from clinics and hospitals.

IV. TELEHEALTH MEDICATION ABORTION AND MINOR CONSENT

As telehealth for MAB becomes more viable, a specific patient population is currently being overlooked in California: minors. Minors in California do not need parental involvement to access MAB, but they may not be able to receive telehealth services without parental consent.[167] This statutory mismatch creates a paradox wherein a minor can consent to a treatment, but not to the modality of its prescription. Because telehealth consent requirements have been temporarily suspended in California under Executive Order by the governor, this is unlikely to become an urgent issue for the duration of the COVID-19 public health emergency.[168] However, this loophole may effectively prevent some minors from accessing MAB via telehealth in the future. As the State looks ahead to a future with fewer restrictions on MAB, it is critical to address this issue.

A. The Minor-TeleMAB Paradox

Under section 123450 of the California Health and Safety Code, minors may not obtain abortion care without parental consent.[169] But in the 1997 case of *American Academy of Pediatrics v. Lungren*, the California Supreme Court found this statute in violation of the California Constitution.[170] The court held that a parental consent statute "impinges upon a fundamental autonomy privacy interest" and "denies a pregnant minor, who believes it is in her best interest to terminate her pregnancy rather than have a child at such a young age, control over her own destiny."[171] The court reasoned that the statute most significantly impacted pregnant minors who were "too frightened or too embarrassed to disclose her condition to a parent (or to a

[167] Am. Acad. of Pediatrics v. Lungren, 940 P.2d 797 (Cal. 1997).

[168] Calif. Exec. Order No. N-43-20 (Apr. 3, 2020), https://www.gov.ca.gov/wp-content/uploads/2020/04/4.3.20-EO- N-43-20-text.pdf.

[169] CAL. HEALTH & SAFETY CODE § 123450.

[170] Am. Acad. of Pediatrics v. Lungren, 940 P.2d 797 (Cal. 1997).

[171] *Id.* at 338-39.

court)."[172] Unlike thirty-seven other states, California does not require parental involvement or judicial authorization for a minor to obtain an abortion.[173]

Because California does not restrict provision of MAB via telehealth, logic dictates that a pregnant minor should be able to legally access TeleMAB services.[174] However, the U.S. Constitution protects the right of parents to consent to the medical treatment of their children.[175] A violation of that right has been found relevant under both the Fourth Amendment and the due process clause of the Fourteenth Amendment.[176] While the U.S. Supreme Court has not defined the exact scope of a parent's right to direct their child's medical care, the Court has consistently acknowledged—and upheld—the existence of that parental right.[177] In California, a minor may not consent to medical care unless the minor is fifteen years old, lives "separate and apart" from parents or guardians, and manages their own finances.[178]

Today, the State permits the use of telehealth for most service provision as long as it is performed by a California licensed physician and complies with state and federal privacy laws.[179] Under section 2290.5 of the Business and Professions Code, a patient must give verbal or written consent to telehealth as a modality of care.[180] However, unlike the State's laws allowing minors to consent to certain sensitive services like abortion as mentioned above, no language exempts the telehealth consent requirement for minors seeking virtual care. Therefore, minors seeking telehealth services for MAB likely still require parental consent.[181]

[172] *Lungren*, 940 P.2d at 314.

[173] *Parental Involvement in Minors' Abortions*, GUTTMACHER INST., https://www.guttmacher.org/state-policy/explore/parental-involvement-minors-abortions (last visited Feb. 28, 2021).

[174] *See, e.g.*, Jeltsen, *supra* note 65 (discussing the solution telemedicine can provide).

[175] Troxel v. Granville, 530 U.S. 57, 66 (2000).

[176] Dubbs v. Head Start, Inc., 336 F.3d 1194, 1222 (10th Cir. 2003).

[177] Emily G. Narum, *Making the Grade: School-Based Telemedicine and Parental Consent*, 53 SAN DIEGO L. REV. 745, 753 (2016).

[178] CAL. FAM. CODE § 6922.

[179] *Practicing Medicine Through Telehealth Technology*, MED. BD. OF CAL., https://www.mbc.ca.gov/Licensees/Telehealth.aspx (last visited Feb. 28, 2021).

[180] CAL. BUS. & PROF. CODE § 2290.5. ("Before the delivery of health care via telehealth, the health care provider initiating the use of telehealth shall inform the patient about the use of telehealth and obtain verbal or written consent from the patient for the use of telehealth as an acceptable mode of delivering health care services and public health. The consent shall be documented.").

[181] For an example of written confirmation of parental consent to telehealth for their minor child, see this form from Bay Area Clinical Associates: https://static1.squarespace.com/static/54650b6ee4b0788b699fe06a/t/5e70e5286a26061dbb406a3d/1584457001997/Telehealth+Consent+-+Minor+%28COVID-19%29.pdf.

B. Recommendation: California Should Close the Loophole and Permit Minor Consent to Telehealth Services for MAB

It is easy to see how this dissonance may be the result of simple oversight, but it is one that should be corrected. Minors are a unique patient population in that they tend to lack autonomy and control over their life situations and are therefore particularly susceptible to delays in abortion care—especially those who do not live near a clinic or hospital, do not have money or means of travel, or are too frightened to tell their parents. Thus, it is especially important that State policies do not obstruct minors from accessing safe, legal abortion care in addition to other services that they can legally consent to without parental involvement. California can ensure minors' rights to obtain an abortion by allowing minors to consent to telehealth provision of MAB without parental consent. A solution should ensure that the State's telehealth consent requirements align with existing laws that allow minors to consent to certain health care services.

This clarification could take the form of an amendment to State telehealth policy, which is dictated by the Telemedicine Development Act of 1996, the Telehealth Advancement Act of 2011, and several subsequent statutes enacted by the legislature.[182] Such an amendment would have substantial grounding in the *Lungren* case, which specifically gives credence to aforementioned concerns about privacy, safety, and infringement on personal autonomy.[183] The State should act to mitigate this complication before the end of the public health emergency, at which time mandatory consent for telehealth will be reinstated.

A counterargument to closing this loophole would be a slippery slope concern: if minors can provide their own consent for telehealth services, then soon enough parents will be completely bypassed in decisions about their children's medical care. This argument is a fallacy. No compelling evidence suggests that *Lungren* has led to significantly less parental involvement in their children's medical care; therefore, there is no reason to expect that the case would be different for telehealth for MAB. Minors should be able to access services they can legally consent to without parental involvement—regardless of the modality by which they receive that care.

[182] CAL. BUS. & PROF. CODE § 2060; *California Policy: Telehealth Advancement Act*, CTR. FOR CONNECTED HEALTH POL'Y, https://www.cchpca.org/telehealth-policy/telehealth-advancement-act (last visited Feb. 28, 2021).

[183] *Lungren*, 940 P.2d at 800.

V. CONCLUSION

"As goes California, so goes the nation."[184] Californians take pride in pioneering and influencing innovative policy on a range of issues, from environmental conservation to cutting-edge technology. While it is true that California is at the forefront of progress in reproductive rights, there is much more we can do to expand access to Californians—and to continue to push the rest of the country forward.

Medication abortion is safe, effective, and, as evidenced by current conditions, has unique power to reach low-income and rural patients. By supporting the collection of no-touch and TeleMAB data during the COVID-19 public health emergency, revisiting the ultrasound requirements for Medi-Cal reimbursement, and closing the loophole preventing minors from accessing TeleMAB, California can lean into its role as a reproductive freedom state. These are feasible solutions that align with the State's commitment to reproductive justice for all.

[184] This common political maxim, here referring to California policy innovation, can be traced to the state of Maine, which once served as a bellwether for U.S. presidential elections. Andrew Glass, *'As Maine goes, so goes the nation,' Sept. 8, 1958*, POLITICO (Sept. 8, 2016), https://www.politico.com/story/2016/09/as-maine-goes-so-goes-the-nation-sept-8-1958-227727.