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CITIZEN PETITION

On May 14, 2025, Secretary of Health and Human Services, Robert F. Kennedy, Jr., testified before the Senate Health, Education, Labor and Pensions Committee that he had ordered the Food and Drug Administration (FDA) to conduct a "complete review" of the medication mifepristone.[1] Mifeprex (mifepristone) and its generic, Mifepristone Tablets, 200 mg (collectively mifepristone) are approved by FDA, in a regimen with misoprostol, to end an intrauterine pregnancy through ten weeks gestation and is currently only available under a single, shared system risk evaluation and mitigation strategy (REMS), known as the Mifepristone REMS Program.[2] Medication abortion using mifepristone is the most common means of abortion in the United States.[3]

In light of FDA's new review of mifepristone, on June 5, 2025, Massachusetts, California, New Jersey, and New York filed a citizen petition pursuant to 21 C.F.R. § 10.30 to request that FDA remove the Mifepristone REMS Program in its entirety. *See* FDA-2025-P-1576, attached hereto as Exhibit 1 (hereinafter, the Mifepristone Multistate Citizen Petition). On consent of the originally-filing states, the State of Washington, along with the states of Arizona, Colorado, Connecticut, Delaware, Hawai'i, Illinois, Maine, Maryland, Michigan, Minnesota, Nevada, New

[1] Hearing on Fiscal Year 2026 Department of Health and Human Services Budget: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions, 119th Cong. (May 14, 2025) (statement of Robert F. Kennedy, Jr., Secretary, Health and Human Services), https://www.help.senate.gov/hearings/hearing-on-fiscal-year-2026-department-of-health-and-human-services-budget (last visited Aug. 19, 2025).

[2] FDA, *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation, AGO-PET01496-1497.

[3] Rachel K. Jones & Amy Friedrich-Karnik, *Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020*, Guttmacher (Mar. 19, 2024), https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020.

Mexico, Oregon, Rhode Island, Vermont, the District of Columbia, and Josh Shapiro in his official capacity as Governor of the Commonwealth of Pennsylvania (together, the Petitioner States) now join the Mifepristone Multistate Citizen Petition.[4]

The Petitioner States did not join the Mifepristone Multistate Citizen Petition when it was filed because the Petitioner States were then engaged in litigation with FDA related to the Mifepristone REMS Program. *See Washington v. FDA*, No. 1:23-cv-03026 (E.D. Wash.). With that litigation now concluded, the Petitioner States now join the Mifepristone Multistate Citizen Petition and incorporate by reference all arguments in that citizen petition herein. *See* Ex. 1.

In addition to joining the Mifepristone Multistate Citizen Petition, the Petitioner States also file this Citizen Petition pursuant to 21 C.F.R. § 10.30 in order to submit further evidence in support of the Mifepristone Multistate Citizen Petition as well as to seek the alternative relief requested below on behalf of Petitioner States. Specifically, the Petitioner States submit evidence on the importance of medication abortion in their states, the safety record of mifepristone in their states, and how the Mifepristone REMS Program unduly burdens patient access and the healthcare delivery system in their states. The Petitioner States also provide an overview of the laws and regulations already in place in their states to ensure that medication abortion is safely prescribed and dispensed. Consistent with the arguments and evidence submitted in the Mifepristone Multistate Citizen Petition, and for the additional reasons set forth below, the Petitioner States ask FDA to either remove the Mifepristone REMS Program, or alternatively, exercise its discretion not to enforce the Mifepristone REMS Program (or elements thereof) in Petitioner States.

ACTION REQUESTED

The Petitioner States request that FDA remove the Mifepristone REMS Program, including but not limited to the Prescriber Certification, Pharmacy Certification, and Patient Agreement form for the reasons set forth below and in the Mifepristone Multistate Citizen Petition (FDA-2025-P-1576). Alternatively, the Petitioner States request that FDA exercise its discretion to not enforce the requirements of the Prescriber Certification, Pharmacy Certification, and Patient Agreement form (or elements thereof) within Petitioner States, which already provide ample protections to ensure patient safety. This requested action will minimize unnecessary and burdensome requirements and maximize access to this critical medication.[5]

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[4] The States of Massachusetts, California, New Jersey, and New York have consented to the Petitioner States joining their citizen petition (FDA-2025-P-1576).

[5] For the reasons stated in the Mifepristone Multistate Citizen Petition and below, FDA should not revert to prior versions of the Mifepristone REMS Program that required additional actions on the part of prescribers, patients, or pharmacies. Nor should FDA add any additional requirements to the current Mifepristone REMS Program.

STATEMENT OF GROUNDS

The Petitioner States join all arguments set forth in the Statement of Grounds in the Mifepristone Multistate Citizen Petition (FDA-2025-P-1576) and incorporate them by reference herein. *See* Ex. 1 at 2-53. The Petitioner States also provide additional information and evidence below in further support of the Mifepristone Multistate Citizen Petition and in support of their requested alternative relief.

I. Medication Abortion is the Primary Means by Which Patients Access Abortion in Petitioner States

Since the United States Supreme Court eliminated federal constitutional protections for abortion in *Dobbs v. Jackson Women's Health Organization*, nearly half of all states have imposed abortion bans or placed significant limits on abortion care.[6] In the Petitioner States, by contrast, abortion remains legal and protected.[7] Maintaining access to mifepristone plays a significant role in ensuring access to reproductive healthcare for patients seeking abortion care or miscarriage management in Petitioner States.

As in Massachusetts, New York, California, and New Jersey, medication abortion is the primary means by which patients access abortion in the majority of Petitioner States. *See* Ex. 1 at 6. For example, in Vermont, approximately 81% of abortions in 2023 were medication abortions.[8] In Delaware, approximately 77% of abortions in 2023 were medication abortions.[9] In Colorado, approximately 72% of abortions in 2023 were medication abortions.[10] In Maine, in

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[6] Nigel Madden et al., *Post-Dobbs Abortion Restrictions and the Families They Leave Behind*, 114 Am. J. of Public Health 1043-50 (2024), https://ajph.aphapublications.org/doi/epdf/10.2105/AJPH.2024.307792.

[7] *See, e.g.*, Wash. Rev. Code § 9.02.100 ("declar[ing] that every individual possesses a fundamental right of privacy with respect to personal reproductive decisions," including the "right to choose or refuse to have an abortion"); Or. Rev. Stat. § 435-240 (state law ensuring that a "consenting individual" cannot be deprived of "the choice . . . to exercise the individuals reproductive health rights under ORS 432.210" nor can a healthcare provider "who is acting within the scope of the health care provider's license" be prohibited from "providing reproductive healthcare information and services"); 775 Ill. Comp. Stat. 55/1-15 (enshrining in statute the right to choose an abortion, recognizing "every individual has a fundamental right to make autonomous decisions about the individual's own reproductive health"); 22 Me. Rev. Stat. § 1598(1) ("It is the public policy of the State [of Maine] that the State not restrict a woman's exercise of her private decision to terminate a pregnancy before viability except as provided in section 1597-A."); *see generally* Center for Reproductive Rights, *After Roe Fell: Abortion Laws by State*, https://reproductiverights.org/maps/abortion-laws-by-state/ (last visited Aug. 19, 2025) (interactive map showing state policies on rights to abortion care).

[8] Vermont Abortion Data, KFF, https://www.kff.org/interactive/womens-health-profiles/vermont/abortion-statistics/ (last visited Aug. 18, 2025).

[9] Amy Friedrich-Karnik, Isabel DoCampo & Candace Gibson, *Medication Abortion Remains Critical to State Abortion Provision as Attacks on Access Persist*, Guttmacher (Feb. 25, 2025), https://www.guttmacher.org/2025/02/medication-abortion-remains-critical-state-abortion-provision-attacks-access-persist.

[10] Colorado Abortion Data, KFF, https://www.kff.org/interactive/womens-health-profiles/colorado/abortion-statistics/ (last visited Aug. 19, 2025).

2023, approximately 70% of abortions were medication abortions.[11] In Connecticut, medication abortion accounted for approximately 69.77% of abortions in 2024 and 68% of abortions in 2023.[12] In Nevada, approximately 69% of abortions in 2023 were medication abortions.[13] In Washington, medication abortion accounted for approximately 68.1% of abortions in 2024 and 66.7% of abortions in 2023.[14] In Maryland, approximately 67% of abortions in 2023 were medication abortions.[15] In Minnesota, approximately 65% of abortions in 2023 were medication abortions.[16] In Oregon, approximately 64.2% of abortions in 2023 were medication abortions.[17] In Illinois, approximately 60% of the abortions in 2023 were medication abortions.[18] In Arizona, approximately 59% of abortions in 2023 were medication abortions.[19] In Pennsylvania, approximately 57% of abortions in 2023 were medication abortions.[20] In New Mexico, approximately 55% of abortions in 2024 were medication abortions.[21] In Michigan, approximately 54.9% of abortions in 2023 were medication abortions.[22] In Rhode Island, approximately 48% of abortions in 2024 were medication abortions.[23] In the District of Columbia, approximately 44% of abortions in 2023 were medication abortions.[24] In Hawai‘i, approximately 36% of abortions in 2023 were medication abortions.[25]

Further, the Mifepristone REMS Program applies to the use of the mifepristone-misoprostol regimen for early miscarriage management. That two-drug regimen is the gold standard of care for early miscarriage management, including in Petitioner States.[26]

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[11] Maine Abortion Data, KFF, https://www.kff.org/interactive/womens-health-profiles/maine/abortion-statistics/ (last visited Aug. 19, 2025).

[12] Decl. of Karyn Backus, Connecticut Department of Public Health (Backus Decl.) ¶¶ 9-10.

[13] Nevada Abortion Data, KFF, https://www.kff.org/interactive/womens-health-profiles/nevada/abortion-statistics/ (last visited Aug. 19, 2025).

[14] Decl. of Samantha Rolland, Washington State Department of Health (Rolland Decl.) ¶¶ 8-9.

[15] Maryland Abortion Data, KFF, https://www.kff.org/interactive/womens-health-profiles/maryland/abortion-statistics/ (last visited Aug. 19, 2025).

[16] Induced Abortions in Minnesota, January-December 2023: Report to the Legislature, Table 13, Minnesota Department of Health, https://www.health.state.mn.us/data/mchs/pubs/abrpt/docs/2023abrpt.pdf (Dec. 31, 2024).

[17] Decl. of Dean E. Sidelinger, Oregon Health Authority (Sidelinger Decl.) ¶ 8.

[18] Illinois Abortion Data, KFF, https://www.kff.org/interactive/womens-health-profiles/illinois/abortion-statistics/ (last visited Aug. 19, 2025).

[19] Arizona Abortion Data, KFF, https://www.kff.org/interactive/womens-health-profiles/arizona/abortion-statistics/ (last visited Aug. 19, 2025).

[20] Decl. of Robert Bonacci, Pennsylvania Department of Health (Bonacci Decl.) ¶ 9.

[21] Decl. of Miranda Durham, MD, New Mexico Department of Health (Durham Decl.) ¶ 7.

[22] Decl. of Elizabeth Hertel, Michigan Department of Health and Human Services (Hertel Decl.) ¶ 9.

[23] Decl. of Zuheil Amorese, Rhode Island State Department of Health (Amorese Decl.) ¶ 8.

[24] District of Columbia Abortion Data, KFF, https://www.kff.org/interactive/womens-health-profiles/district-of-columbia/abortion-statistics/ (last visited Aug. 18, 2025).

[25] Decl. of Grace Marie Vo, MBA, PMP, SPHR, State Registrar and Chief, Office of Health Status Monitoring, Department of Health, State of Hawai‘i (Vo Decl.) ¶ 9.

[26] *See generally* Schreiber, C.A., Creinin, M.D., Atrio, J., Sonalkar, S., Ratcliffe, S.J., Barnhart, K.T., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 New Engl. J. Med. 2161–70

II. Medication Abortion Is Safe in Petitioner States

A. FDA Has Long Recognized That Mifepristone's Safety Profile Is Well-Characterized and Major Adverse Events Are Extremely Rare

As discussed extensively in the Mifepristone Multistate Citizen Petition, the safety of mifepristone over the last 25 years is incredibly well documented. *See* Ex. 1 at 2-3, 12-16. For example, when FDA conducted its medical review of mifepristone in 2016, it found: "[Mifeprex] has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare."[27] FDA observed at that time that "[m]ajor adverse events . . . are reported rarely in the literature on over 30,000 patients. The rates, when noted, are exceedingly rare, *generally far below 0.1%* for any individual adverse event."[28] FDA further stated that "[t]he safety profile of Mifeprex is well-characterized and its risks well-understood after more than 15 years of marketing. Serious adverse events are rare and the safety profile of Mifeprex has not substantially changed."[29] Since FDA's 2016 medical review (which was based on 2.5 million uses at the time), mifepristone has been used ***an additional five million times*** in the United States.[30]

From the time mifepristone was approved in 2000 through December 2024, there have only been thirty-six reported associated deaths out of 7,500,000 uses—an associated fatality rate of **0.00048%**. Further, FDA acknowledges that *none* of these deaths can be "causally attributed" to mifepristone.[31]

Leading medical organizations with reproductive care expertise have also recently reaffirmed the continued safety of mifepristone. In May 2025, thirteen leading medical organizations, including the largest professional association of providers specializing in obstetrics and gynecology in the United States with more than 60,000 members, issued a joint statement "urg[ing] availability of mifepristone that is equitable" and "free from needlessly

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(2018), AGO-PET00343-352; Elise W. Boos et al., *Trends in the Use of Mifepristone for Medical Management of Early Pregnancy Loss From 2016 to 2020*, 330 JAMA 766 (2023), AGO-PET00960-962.

[27] Ctr. for Drug Evaluation & Rsch., FDA, Application No. 020687Orig1s020 Mifeprex Medical Review(s) 12 (Mar. 29, 2016), AGO-PET00486.

[28] *Id.* at 47, AGO-PET00574 (emphasis added).

[29] FDA, Ctr. for Drug Evaluation & Research, 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s): REMS Modification Memorandum at 3 (Mar. 29, 2016), AGO-PET00708.

[30] FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2024* 1, https://www.fda.gov/media/185245/download), AGO-PET01197.

[31] *Id.*; *see also Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Feb. 11, 2025), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation, AGO-PET03190-3202.

burdensome restrictions."[32] Specifically, those organizations advocated that FDA approval of mifepristone "reflect the rigorous clinical evidence that has proven unequivocally that it is safe and effective for use in medication abortion and miscarriage management."[33] Several of these organizations also filed a citizen petition earlier this year, once again asking FDA to remove the Mifepristone REMS Program.[34] FDA should meaningfully consider the expertise of these organizations and their member practitioners, many of whom practice in Petitioner States.[35]

B. Data Collected by the Departments of Health in Petitioner States Provide Further Evidence of Mifepristone's Safety

Additional evidence of mifepristone's safety is reflected in the declarations provided by the departments of health of several of the Petitioner States. As discussed below, state departments of health that collect information on abortion consistently report serious adverse events related to medication abortion to be very rare. Instead, the most common complication reported is retained products of conception, which is not an adverse safety event.[36] State departments of health also report that serious adverse events have remained low following the introduction of telemedicine in their states.

For instance, the Washington Department of Health (Washington DOH) tracks data related to abortions in Washington, including the number of abortions, the method of abortion, and any abortion complications.[37] Washington providers are required to report abortion complications to the Washington DOH, including instances of hemorrhage, infection, failed abortion (continuing pregnancy), death, and retained products of conception.[38] Washington providers must also report how they managed any complications, including whether the patient

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[32] Press Release, Am. Coll. Obstetricians & Gynecologists et al., *Leading Medical Organizations Reaffirm the Safety of Mifepristone* (May 22, 2025), https://www.acog.org/news/news-releases/2025/05/leading-medical-organizations-reaffirm-the-safety-of-mifepristone, AGO-PET03176-3178.

[33] *Id.*

[34] FDA-2025-P-0377-0001, Citizen Petition from Sandra E. Brooks, Chief Exec. Officer, Am. Coll. of Obstetricians & Gynecologists, et al. to FDA (Jan. 31, 2025), AGO-PET00256-285.

[35] *See* FDA, *REMS: FDA's Application of Statutory Factors in Determining When a REMS is Necessary*, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fdas-application-statutory-factors-determining-when-rems-necessary (Apr. 2019), AGO-PET-01147-1148 (explaining that in making a REMS determination FDA may take into consideration information from a variety of sources including "professional societies").

[36] Retained products of conception is considered an "an incomplete medication abortion," which can be treated with a repeat dose of misoprostol, uterine aspiration, or expectant management, depending on the clinical circumstances and patient preference. *See generally* Committee on Practice Bulletins—Gynecology and the Society of Family Planning, *Practice Bulletin 225, Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology e31, e38 (Oct. 2020), AGO-PET00322-338. Ongoing pregnancy after medication abortion can be treated with a repeat dose of misoprostol or uterine aspiration, depending on the clinical circumstances and patient preference. *Id.* An incomplete medication abortion is not an adverse safety event. *See id.*; *infra* n.97.

[37] *See* Wash. Admin. Code § 246-490-100; *see also* Rolland Decl. ¶¶ 5-6 (discussing data).

[38] Wash. Admin. Code § 246-490-100.

was hospitalized or given a transfusion.[39] The Washington DOH uses this data to examine trends in public health and to improve access to reproductive healthcare services in Washington.[40]

In 2024, 14,563 medication abortions in Washington involved the use of mifepristone.[41] Of these medication abortions, providers reported complications in only 135 cases, with the two most commonly-reported complications being retained products of conception and failed abortion, neither of which are adverse events.[42] Fewer than 0.2% of medication abortions in Washington in 2024 resulted in a complication severe enough to warrant hospitalization and fewer than 0.2% resulted in a complication requiring a blood transfusion.[43]

In 2023, 14,208 medication abortions in Washington involved the use of mifepristone.[44] Of these abortions, providers reported complications in only 182 cases, with the two most commonly-reported complications being retained products of conception and failed abortion.[45] As in 2024, fewer than 0.2% of medication abortions in 2023 resulted in a complication severe enough to warrant hospitalization and fewer than 0.2% resulted in a complication requiring a blood transfusion.[46]

The safety of mifepristone is further reflected in abortions provided via telemedicine, which has also increased access to abortion in Washington, particularly for those in rural and medically-underserved parts of the state.[47] In Washington in 2024, for instance, at least 3,011 medication abortions were reported as being performed by telemedicine.[48] *None* of the 3,011 medication abortions that were reported as being provided via telemedicine in 2024 resulted in a complication severe enough to warrant hospitalization.[49] The same was true in 2023 and 2022: none of the medication abortions that were reported as being provided via telemedicine in those years resulted in a complication severe enough to warrant hospitalization.[50]

Pennsylvania collects similar data on abortion.[51] Abortion providers in Pennsylvania are required to report all abortions to the Pennsylvania Department of Health (Pennsylvania DOH) as well as all abortion-related complications, including infection, retained products of

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[39] Rolland Decl. ¶ 5.
[40] *Id.* ¶ 6.
[41] *Id.* ¶ 8.
[42] *Id.*; *see also supra* n.36.
[43] Rolland Decl. ¶ 8.
[44] *Id.* ¶ 9.
[45] *Id.*
[46] *Id.*
[47] *See id.* ¶¶ 13-16.
[48] *Id.* ¶ 13 & n.2.
[49] *Id.* ¶ 13.
[50] *Id.* ¶¶ 14-15.
[51] *See* 18 Pa. Cons. Stat. § 3214(a), (b); 28 Pa. Code § 29.38(a)(3); *see also* Bonacci Decl. ¶¶ 5-6.

conception, bleeding, and "other."[52] If there are any complications, Pennsylvania providers must report to the Pennsylvania DOH how the complication was managed.[53] This data is used to examine trends in public health and improve access to reproductive healthcare services within the state.[54]

In 2023, of the 19,993 medication abortions provided in Pennsylvania, providers reported complications in only 342 cases, with the vast majority of those complications being retained products of conception.[55] Likewise, in 2022, of the 19,011 medication abortions performed in Pennsylvania, providers reported complications in only 270 cases, with the vast majority of complications being retained products of conception.[56] The data from additional years is similar.[57] Indeed, from 2017-2023, complications related to medication abortion have consistently remained very low with the vast majority of complications being retained products of conception.[58]

In Hawai‘i, abortion providers are required to report data to the State of Hawai‘i, Department of Health (Hawai‘i DOH), including the method of abortion.[59] Abortion complications that providers report to the Hawai‘i DOH include hemorrhage, infection, failed abortion, continuing pregnancy, death, and retained products of conception.[60] In 2023, there were 3,005 abortions that were reported to the Hawai‘i DOH. Of these, 1088 were medication abortions involving the use of mifepristone.[61] Of the 1,088 medication abortions, only fourteen reported complications with the most commonly reported complication being retained products of conception.[62] In 2022, of the 988 medication abortions in Hawai‘i, there were only eleven reported complications, with the most common complication being retained products of conception.[63] In addition, the Hawai‘i Medicaid program reviewed abortion data from January 2023 through July 2025 regarding adverse events from its managed care plans, and is aware of no adverse events related to mifepristone.[64] The low rate of complications for medication abortion has remained consistent following the introduction of telemedicine for medication abortions in Hawai‘i.[65]

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[52] *Id.* ¶ 5.
[53] *Id.*
[54] *Id.* ¶ 6.
[55] *Id.* ¶ 9.
[56] *Id.* ¶ 10.
[57] *Id.* ¶¶ 11-15.
[58] *Id.* ¶ 16; *see also id.* ¶¶ 9-15.
[59] *See* Haw. Rev. Stat. §338-9.
[60] *See* Vo Decl. ¶ 4.
[61] *Id.* ¶ 8.
[62] *Id.*
[63] *Id.* ¶ 9.
[64] *See* Decl. of Judy Mohr Peterson, Medicaid Director, Department of Human Services, State of Hawai‘i (Mohr Peterson Decl.) ¶ 4.
[65] *Id.* ¶¶ 4-6; Vo Decl. ¶¶ 12-13.

The Rhode Island State Department of Health (RIDOH) collects data on abortions, including the number of abortions, the methods, and the rates of complications. In 2022-2024, the most common complication reported with medication abortion was retained products of conception.[66] "[S]erious complications related to the use of mifepristone in medication abortion in Rhode Island have consistently remained very low, even as the number of medication abortions involving mifepristone has increased."[67] The rate of serious complications has also remained low even as telemedicine for medication abortions was introduced in Rhode Island.[68] Further, "the provision of medication abortion via telemedicine has increased access to abortion in Rhode Island," and "[a]ny decrease in the availability of abortion medication via telemedicine would decrease access to abortion in Rhode Island."[69]

The New Mexico Department of Health (NMDOH) collects data on abortions, with all abortion providers required to report abortions within five days of the abortion occurring.[70] New Mexico "is not in possession of any data that indicate there are serious complications related to mifepristone abortion in New Mexico, even as the number of mifepristone abortions has consistently increased."[71] Further, New Mexico permits medication abortions performed by telehealth.[72] "The provision of medication abortion via telemedicine has increased access to abortion in New Mexico, particularly for those in rural and medically-underserved areas."[73] "Any decrease in the availability of abortion medication via telemedicine would decrease access to abortion in New Mexico for underserved patients and rural communities."[74]

The Oregon Health Authority (OHA) also collects data on abortion. Abortion providers in Oregon are required to report data on abortions provided in Oregon to OHA, including the method of the abortion and any complications.[75] Abortion complications that a provider is required to report to OHA include hemorrhage, infection, failed abortion (continuing pregnancy), death, and retained products of conception.[76] The two most common complications reported in Oregon in 2020-2024 were failed abortion or retained products of conception, neither of which are considered to be serious complications.[77] As reflected by this data, "[s]erious complications related to medication abortion involving the use of mifepristone in Oregon have consistently

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[66] Amorese Decl. ¶¶ 8-10.
[67] *Id.* ¶ 12.
[68] *Id.* ¶ 13.
[69] *Id.* ¶ 14.
[70] Durham Decl. ¶ 4; *see also* N.M. Stat. Ann. § 24-14-18.
[71] *Id.* ¶ 12.
[72] *Id.* ¶ 13.
[73] *Id.* ¶ 14.
[74] *Id.*
[75] Or. Rev. Stat. § 432.153 & Or. Rev. Stat. § 435.496 ; *see also* Sidelinger Decl. ¶ 4.
[76] Sidelinger Decl. ¶ 4.
[77] *Id.* ¶¶ 7-11; *see also supra* n.36.

remained very low, even as the number of mifepristone abortions has significantly increased."[78] And notably, "[t]his low rate of complications has also remained consistent following the introduction of telemedicine for mifepristone abortions in Oregon."[79]

Finally, the Connecticut Department of Public Health (DPH) collects data on abortions. All outpatient abortion clinics are required to report data to DPH.[80] While reporting on abortion complications is no longer required in Connecticut, "during the period when DPH collected data on abortion complications, the reported serious complications related to mifepristone abortion in Connecticut were very low."[81] For instance, in 2021, of the 6,163 medication abortions reported to DPH, only three reported complications.[82] In 2020, of the 5,561 medication abortions, only two reported complications.[83] In both 2020 and 2021, the only reported complications were retained product of conception and failed abortion.[84]

In sum, as consistently reflected in this public health data, serious adverse events associated with mifepristone in Petitioner States are extremely rare, and instead the most common complication is retained products of conception, which is not an adverse safety event. Further, there has been no increase in serious adverse events following the introduction of telemedicine, and state departments of health testify that the provision of medication abortion via telemedicine has increased access to abortion for those in rural and medically-underserved areas and that a decrease in the availability of telemedicine for medication abortion would burden abortion access for those populations.[85]

C. No Reliable Scientific Data Alters the Conclusion That Mifepristone Is Safe in Petitioner States

The data on the safety of medication abortions, collected by many state health departments, are consistent with the longstanding clinical data that underly the broad scientific

[78] Sidelinger Decl. ¶ 12.
[79] *Id.* ¶ 13.
[80] Backus Decl. ¶ 7.
[81] *Id.* ¶ 13.
[82] *Id.* ¶ 12.
[83] *Id.* ¶ 13.
[84] *Id.* ¶ 12-13.
[85] Numerous studies likewise confirm that telehealth provides an important care option for patients living in rural and medically underserved areas who would otherwise have to travel long distances to receive in-person care. *See* Ex. 1 at 15-16 & nn. 86-90; *see also* Koenig, Leah R. et al., *Patient Acceptability of Telehealth Medication Abortion Care in the United States, 2021-2022: A Cohort Study*, 114 Am. J. Pub. Health 241, 247-48 (2024); Amy Tressan et al., *Telemedicine Abortion in Primary Care: An Exploration of Patient Experiences*, 22 Annals of Fam. Med. 19 (2024); Emily M. Godfrey et al., *Patient Perspectives Regarding Clinician Communication During Telemedicine Compared With In-Clinic Abortion*, 141 Obstetrics & Gynecology 1139, 1143 (2023), AGO-PET01036-1053; Leah R. Koenig et al., *The Role of Telehealth in Promoting Equitable Abortion Access in the United States: Spatial Analysis*, 9 JMIR Pub. Health Surveillance e45671 (2023), AGO-PET01758-1769.

consensus on mifepristone's well-established safety record. This stands in sharp contrast to the recent self-published paper by the Ethics and Public Policy Center (EPPC) which relied on an "all-payer insurance claims" database to purportedly conclude that 10.93% of women experience a "serious adverse event" after taking mifepristone.[86] The Mifepristone Multistate Citizen Petition and other commenters explain the multiple reasons that the EPPC paper is gravely unreliable.[87] Moreover, unlike EPPC—whose confessed mission it is to "advance pro-life policies" by "restricting abortion at the state and federal levels"—the mission of state departments of health is to protect and improve the health of all of the individuals within their states.[88] Thus, unlike EPPC, state health departments have no incentive to manipulate or interpret public health data to achieve a particular outcome; instead their goal is to ensure that health care is delivered safely and effectively to individuals within their states. The neutral evaluation of abortion-related data by state health departments is compelling evidence of mifepristone's ongoing safety in Petitioner States.[89]

For similar reasons, the comment letter submitted by the Charlotte Lozier Institute (CLI) in opposition to the Multistate Mifepristone Citizen Petition and in support of restoring previously removed Elements to Assure Safe Use (ETASU) does not alter this conclusion.[90] In its

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[86] Jamie Bryan Hall & Ryan T. Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, 1 Ethics and Public Policy Center 1 (2025), https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf, AGO-PET01539.

[87] *See* Ex. 1 at 16-21; Ushma Upadhyay Comment Letter on Citizen Petition; American College of; Obstetricians and Gynecologists; Society of Family Planning; Society for Maternal-Fetal Medicine Request that FDA remove the Mifepristone Shared System REMS Program (April 30, 2025), https://www.regulations.gov/comment/FDA-2025-P-0377-0017.

[88] *Compare* Life and Family Initiative, Ethics & Pub. Pol'y Ctr., https://eppc.org/program/life-and-family-initiative/ (last visited Aug. 19, 2025) (discussing their "pro-life" agenda) *with* Washington State Department of Health, Vision, Mission and Values, https://doh.wa.gov/about-us/vision-mission-and-values (last visited Aug. 19, 2025) ("The Department of Health works with others to protect and improve the health of all people in Washington state.") *and* Pennsylvania State Department of Health, About the Department of Health, https://www.pa.gov/agencies/health/about-us#accordion-b758c19c71-item-c2f465d5de (last visited Aug. 19, 2025) ("The mission of the Pennsylvania Department of Health is to promote healthy behaviors, prevent injury and disease, and to assure the safe delivery of quality health care for all people in Pennsylvania.") and Oregon Health Authority, About OHA, https://www.oregon.gov/oha/pages/portal-about-oha.aspx (last visited Aug. 19, 2025) ("The Oregon Health Authority is at the forefront of lowering and containing costs, improving quality and increasing access to health care in order to improve the lifelong health of people in Oregon.").

[89] *See generally* FDA, *REMS: FDA's Application of Statutory Factors in Determining When a REMS is Necessary*, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fdas-application-statutory-factors-determining-when-rems-necessary (Apr. 2019), AGO-PET01147-1148 (explaining that in making a REMS determination FDA make take into consideration information from a variety of sources including "other government agencies"), AGO-PET01147-1147.

[90] CLI Comment Letter on Citizen Petition: Attorney General of Massachusetts; Attorney General of California; Attorney General of New Jersey; Attorney General of New York; Request that the FDA remove the Mifepristone REMS Program (July 24, 2025) (hereinafter, CLI Comment Letter); *see also* Charlotte Lozier Institute, About Lozier Institute, https://lozierinstitute.org/about/ (last visited Aug. 19, 2025) ("Charlotte Lozier Institute advises and leads the pro-life movement . . . .").

comment letter, CLI, an advocacy organization that identifies as part of the "pro-life movement,"[91] raises a hodgepodge of objections to the Multistate Mifepristone Citizen Petition and defends the retracted studies of researchers associated with CLI.[92] Broadly, the CLI comment letter would have FDA ignore the robust record of high-quality scientific evidence and decades of patient data supporting mifepristone's safety and efficacy, and instead rely on its own flawed studies by biased and discredited authors. While none of CLI's objections are availing, Petitioner States provide responses to a few of their arguments to demonstrate the general unreliability of CLI's comment letter and the studies that they tout.

First, CLI contends that "[m]ifepristone safety data is severely deficient and undercounts true complication rates."[93] In support of this assertion, CLI points to a study that purports to show a significant gap between adverse-event data compiled by abortion providers and adverse-events that were reported to FDA and included in the Federal Adverse Events Reporting System (FAERS) during 2009-2010.[94] But their assertion that FAERS contained only "half as many adverse events" as other provider reporting is misleading.[95] The only category identified in that study for which adverse event reporting in FAERS was purportedly deficient was in cases of "ongoing pregnancy" after mifepristone use, [96] which is *not* a serious safety event.[97] Although

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[91] Charlotte Lozier Institute, About Lozier Institute, https://lozierinstitute.org/about/ ("Charlotte Lozier Institute advises and leads the pro-life movement . . . .").

[92] Authors affiliated with CLI have had their work retracted for serious methodological flaws, including "fundamental problems with the study design and methodology, unjustified or incorrect factual assumptions, material errors in the authors' analysis of the data, and misleading presentations of the data that . . . demonstrate a lack of scientific rigor and invalidate the authors' conclusions in whole or in part." *See* Sage Journals, Retraction Notice: https://journals.sagepub.com/doi/10.1177/23333928231216699; RETRACTED: *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999–2015*, https://journals.sagepub.com/doi/full/10.1177/23333928211053965; RETRACTED: *A Post Hoc Exploratory Analysis: Induced Abortion Complications Mistaken for Miscarriage in the Emergency Room are a Risk Factor for Hospitalization*, https://journals.sagepub.com/doi/10.1177/23333928221103107.

[93] CLI Comment Letter at 3.

[94] *Id.* (citing Christina A. Cirucci, Kathi A. Aultman, Donna J. Harrison, *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act*, 8 Health Serv Res Manag Epidemiol. 1-5 (Dec. 21, 2021)).

[95] *Id.* Additionally, this study was coauthored by Dr. Donna Harrison, whose testimony on abortion has been discredited by courts across the country, which have found her expert opinions inaccurate, unsupported by research, and distorted to serve her ideological goals. *See infra* at 21.

[96] *See* Christina A. Cirucci, Kathi A. Aultman, Donna J. Harrison, *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act*, 8 Health Serv Res Manag Epidemiol. 1-5 (Dec. 21, 2021) (Table 1).

[97] As reflected in the FDA-approved labeling for Mifeprex, an ongoing pregnancy is an outcome related to the medication's effectiveness, not an adverse event impacting mifepristone's safety. FDA, *Mifepristone 2023 Labeling and Medication Guide* 16 (2023), AGO-PET01178-1196 (compare Table 2 (Adverse reactions) (AGO-PET01185) with Table 3 (Outcome Following Treatment) (AGO-PET01190); *see also* FDA Ctr. for Drug Evaluation & Rsch., FDA, Application No. 020687Orig1s020 Mifeprex Medical Review(s) 47 (Mar. 29, 2016) (describing

mifepristone is approximately 97% effective, some patients will have an ongoing pregnancy after its use.[98] But an ongoing pregnancy is *not* evidence that mifepristone is unsafe, just that the patient may require additional medical treatment such as an additional dose of misoprostol or uterine aspiration.[99]

Further, as discussed above, many of the departments of health within Petitioner States require abortion providers to report complications or adverse events. *Supra* at 6-10. And, notably, those states—like FDA's medical review team[100]—have determined that serious adverse events from mifepristone are extremely rare. *Id.*[101] Instead, the most commonly reported complication is retained products of conception, which is not an adverse safety event. *Id.*[102] Nor have those states observed an increase in safety incidents following the introduction of telemedicine. *Id.*[103]; *see*

"major adverse events" as "death, hospitalization, serious infection, bleeding requiring transfusion and ectopic pregnancy with the proposed regimen"), AGO-PET00521; *see also id*. at 50 (similarly defining serious adverse events); *id.* at 35 (listing "ongoing pregnancy" as an "efficacy outcome").

[98] *See* FDA Ctr. for Drug Evaluation & Rsch., FDA, Application No. 020687Orig1s020 Mifeprex Medical Review(s) 29 (Mar. 29, 2016), AGO-PET00503; *see also* Ex. 1 at 9 n.47.

[99] *See supra* n.36 (discussing treatment for ongoing pregnancy following an incomplete medication abortion); *see also, e.g.*, Elizabeth G. Raymond et al., *First-Trimester Medical Abortion with Mifepristone 200 mg and Misoprostol: A Systematic Review*, 87 Contraception 26 (2013) (noting "the low overall risk of medical abortion failure and relative ease of treating failure using surgical evacuation (which would have been the treatment for all subjects had medical abortion not been attempted)"), AGO-PET00973.

[100] *See* Ctr. for Drug Eval. & Rsch., FDA, *Application No. 020687Orig1s020: Risk Assessment and Risk Mitigation Review(s)*: REMS Modification Memorandum at 3 (Mar. 29, 2016), AGO-PET00708 (concluding that that "[t]he safety profile of Mifeprex is well-characterized and its risks well-understood after more than 15 years of marketing" and that "[s]erious adverse events are rare and the safety profile of Mifeprex has not substantially changed").

[101] *See* Amorese Decl. ¶¶ 8-13 ("[S]erious complications related to the use of mifepristone in medication abortion in Rhode Island have consistently remained very low, even as the number of medication abortions involving mifepristone has increased"); Backus Decl. ¶¶ 12-13 ("during the period when DPH collected data on abortion complications, the reported serious complications related to mifepristone abortion in Connecticut were very low"); Bonacci Decl. ¶¶ 9-16, 18-20 (complications related to medication abortion in Pennsylvania have "consistently remained very low"); Durham Decl. ¶¶ 7-12 ("[New Mexico Department of Health] is not in possession of any data that indicate there are serious complications related to mifepristone abortion in New Mexico, even as the number of mifepristone abortions has consistently increased."); Mohr Peterson Decl. ¶¶ 4, 6 ("adverse events related to mifepristone abortion in the Hawai'i Medicaid population have remained very low, if any, even as the number of mifepristone abortions has generally increased"); Rolland Decl. ¶¶ 8-15 ("serious complications related to medication abortions involving the use of mifepristone in Washington have consistently remained very low, even as the number of medication abortions involving the use of mifepristone has consistently increased"); Sidelinger Decl. ¶¶ 7-13 (similar); Vo. Decl. ¶¶ 8-13 (similar).

[102] *See* Amorese Decl. ¶¶ 8-10; Bachus Decl. ¶¶ 12-13; Bonacci Decl. ¶¶ 9-15; Rolland Decl. ¶¶ 8-11; Sidelinger Decl. ¶¶ 7-11; Vo Decl. ¶¶ 8-11.

[103] *See* Amorese Decl. ¶ 13 ("This low rate of complications has also remained consistent following the introduction of telemedicine for mifepristone abortions in Rhode Island."); Mohr Peterson Decl. ¶¶ 4, 6; Rolland Decl. ¶¶ 13-15 (similar); Sidelinger Decl. ¶ 13 (similar); Vo Decl. ¶¶ 13 (similar); *see also* Durham Decl. ¶¶ 12-14.

also Ex. 1 at 12-16 (reviewing recent research confirming that medication abortion care provided by telehealth is highly safe and effective).[104]

It also bears noting that the "[h]igh quality studies" that CLI relies on for its purported safety concerns actually underscore mifepristone's overall safety.[105] For instance, in the Raymond study cited in footnote 11, the authors concluded that medication abortion using mifepristone followed by misoprostol is "remarkably effective and safe" and that in "trials that together included more than 45,000 women conducted in disparate settings over nearly two decades" the rate of "[s]erious complications requiring hospitalization or transfusion occurred in less than 0.4% of patients."[106] The other studies similarly conclude that "the risk for serious

[104] Since FDA's decision to eliminate the in-person dispensing ETASU in December 2021, a growing body of research has confirmed that the dispensing of mifepristone via telehealth is safe and effective. *See, e.g.*, Ushma Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182 JAMA Internal Med. 482, 482 – 491 (2022), AGO-PET03478-3487; Abigail R.A. Aiken et al., *Safety and effectiveness of self-managed medication abortion provided using online telemedicine in the United States: A population based study*, 10 Lancet Regional Health – Americas 1, 1-7 (2022), AGO-PET00009-16; Jane W. Seymour et al., *Potential Impact of Telemedicine for Medication Abortion Policy and Programming Changes on Abortion Accessibility in the United States*, 112 Am. J. Public Health. 1202, 1202-1211 (2022), AGO-PET01553-1562; Samantha Ruggiero et al., *Patient and Provider Experiences Using a Site-to-site Telehealth Model for Medication Abortion*, 8 mHealth 1, 1 – 9 (2022), AGO-PET03246-3255; Courtney Kerestes et al., *Person-centered, high-quality care from a distance: A qualitative study of patient experiences of TelAbortion, a model for direct-to-patient medication abortion by mail in the United States*, 54 Perspectives Sexual & Reprod. Health 177, 177 – 187 (2022), AGO-PET00357-369; Marit Pearlman Shapiro et al., *No-Test Medication Abortion: A Systemic Review*, 141 Obstetrics & Gynecology 23 (2023); Leah R. Koenig et al., *Mailing Abortion Pills Does Not Delay Care: A Cohort Study Comparing Mailed to In-person Dispensing of Abortion Medications in the United States*, 121 Contraception 1, 1-7 (May 2023), AGO-PET01743-1757; Ushma Upadhyay et al., *Effectiveness and Safety of Telehealth Medication Abortion in the United States*, 30 Nature Med. 1191, 1192, 1193, 1196 (2024), AGO-PET03433-3452; Martha K. Smith et al., *The Safety and Efficacy of a "No Touch" Abortion Program Implemented in the Greater Toronto Area During the COVID-19 Pandemic*, 46 J. Obstetrics & Gynaecology Can. 1 (2024); Leonardo Cely-Andrade et al., *Telemedicine for the Provision of Medication Abortion to Pregnant People at up to Twelve Weeks of Pregnancy: A Systematic Literature Review and Meta-Analysis*, 21 Reprod. Health 136, 155 (2024); Lauren J. Ralph et al., *Comparison of No-Test Telehealth and In-Person Medication Abortion*, 332 JAMA 898, 903 (2024), AGO-PET01793-1800; Caitlin Hunter et al., *Test or No-Test: Comparison of Medication Abortion Outcomes and Adverse Events When Forgoing Ultrasound, Laboratory Testing, and Physical Examination*, 47 J. Obstetrics & Gynaecology Can. 1, 7 (2025); *see also* Silpa Srinivasulu et al., *Telehealth Medication Abortion in Primary Care: A Comparison to Usual in-Clinic Care*, 37 J. of the Am. Board of Fam. Med. 295, 299 (2024), AGO-PET03343-3350.

[105] CLI Comment Letter at 3-4 & nn.10-11.

[106] Elizabeth G. Raymond et al., *First-Trimester Medical Abortion with Mifepristone 200 mg and Misoprostol: A Systematic Review*, 87 Contraception 26 (2013), AGO-PET00972.

adverse outcomes is very small"[107] and "termination of pregnancy by means of either medical or surgical methods is associated with a low level of serious complications."[108]

Second, CLI baselessly contends that greater access to mifepristone could "increase, not lower, maternal mortality."[109] To do so, they first cast aspersions on the maternal mortality data collected by the Centers for Disease Control (CDC), vaguely positing there may be a "more comprehensive way" to collect maternal mortality data.[110] This suggestion does not change the fact that the federal government's own data demonstrates that the risk of death in pregnancy or labor in the United States is ***far greater*** than the risk of death with abortion: 18.6 deaths per 100,000 live births compared to 0.46 deaths per 100,000 legal abortions.[111] And as explained in the Multistate Mifepristone Citizen Petition, not only can pregnancy be deadly, it also poses significant dangers short of death.[112] It is beyond dispute that there are many health risks associated with any ongoing pregnancy, including high blood pressure, gestational diabetes, infections, preeclampsia, preterm labor, and depression and anxiety.[113] And approximately 1.6% of women giving birth in U.S. hospitals experience severe maternal morbidity—including

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[107] Ning Liu & Joel G. Ray, *Short-Term Adverse Outcomes After Mifepristone-Misoprostol Versus Procedural Induced Abortion: A Population-Based Propensity-Weighted Study*, 176 Ann Intern Med. 145-53 (Jan. 3, 2023) (cited in CLI Comment Letter at 4 n.10) (concluding that "although short-term adverse events occur more often after mifepristone–misoprostol [induced abortion] IA than procedural [induced abortion] IA, the risk for serious adverse outcomes is very small"; also noting that "indicators of risk should be balanced by other considerations, such as regional availability of procedural IA, travel time, financial cost, and a woman's preferences and psychological wellbeing").

[108] Maarit Niinimäki et al., *Immediate Complications After Medical Compared With Surgical Termination of Pregnancy*, 114 Obstet. Gynecol. 795-804 (2009) (cited in CLI Comment Letter n.11) (reviewing pregnancy termination data in Finland between 2000-2006; concluding that "termination of pregnancy by means of either medical or surgical methods is associated with a low level of serious complications"); *see infra* at 19 (discussing the reporting of abortion complications in Finland); *see also* Melissa J. Chen & Mitchell D. Creinin, *Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review*, 126 Obstet. Gynecol. 12-21 (July 2015) (cited in CLI Comment Letter n.11) (reviewing data between 2005-2015 and concluding "[b]lood transfusion and infection are uncommon, occurring in approximately 0.03-0.6% and 0.01-0.5% of patients, respectively" and "[a]dverse outcomes of emergency department visits (2.9–3.7%) and hospitalizations (0.04-0.9%) are inconsistently reported with variable rates across studies").

[109] CLI Comment Letter at 2.

[110] *Id.*

[111] *See* Nat'l Ctr. for Health Stat., CDC, Health E-Stats: Maternal Mortality Rates in the United States, 2023 6 (Feb. 2025) (maternal mortality rate of 18.6 death per 100,000 live births), AGO-PET02583-2589; Stephanie Ramer et al., *Abortion Surveillance — United States, 2022*, 73 Morbidity & Mortality Weekly Rep. Surveillance Summaries 1, 6 (Nov. 28, 2024) ("During 2013–2021, the national case-fatality rate for legal induced abortion was 0.46 deaths related to legal induced abortions per 100,000 reported legal abortions."), AGO-PET03373, AGO-PET03378-3379; *see also* Ex. 1 at 7-9 & n.42 (discussing this data and explaining that causes of pregnancy-related deaths in the United States include cardiovascular conditions, infection or sepsis, hemorrhage, cardiomyopathy, thrombotic pulmonary or other embolisms, hypertensive disorders of pregnancy, amniotic fluid embolism, cerebrovascular accidents, and anesthesia complications (citing CDC, Pregnancy Mortality Surveillance System 4 (Nov. 14, 2024), AGO-PET000201-208)).

[112] Ex. 1 at 7-8 (discussing health risk associated with pregnancy).

[113] *See id.*

hemorrhage, hysterectomy, acute respiratory distress syndrome, acute kidney failure, sepsis, eclampsia, shock, and acute heart failure or pulmonary edema.[114] CLI ignores these risks and points to no data showing that serious risks attend mifepristone at anywhere near the same rates.

Unable to meaningfully rebut this safety gap, CLI contends that "*[i]n the year following abortion* compared to childbirth, a woman is 2-4 times as likely to die from any cause and six times as likely to die from suicide." Comment Letter at 17 (emphasis added). But that statistic, which was taken from a publication by Dr. Ingrid Skop—whose testimony on abortion safety has been rejected by a court as "inaccurate and overstated," *see infra* at 20-21(discussing Dr. Skop)—is highly flawed. First, it was plucked from decades-old Finnish studies based on reviews of Finnish death certificates between 1987 and 1994.[115] And second, as Dr. Skop admitted in a 2020 deposition, the Finnish studies do not assess a causal relationship between a history of abortion or pregnancy and an outcome of any kind.[116] Instead, the studies identify only "pregnancy-associated" or "abortion-associated" deaths, which she explains is a death within one year "irrespective of the cause."[117] Thus, she agreed that the Finnish studies would include a patient "who gets hit by a car outside of the hospital as a pregnancy-related cause" because it includes all deaths.[118]

Further, when a 2002 study of California Medicaid recipients attempted to "replica[t]e" the findings of the Finnish studies (based on data that pre-dated mifepristone's FDA approval), one of that study's co-authors—Dr. Priscilla Coleman—later admitted under oath that the study's claim that "higher death rates associated with abortion persist over time" was merely a hypothesis and "*wasn't a statement that was based on the actual findings*."[119] The unreliability of that study is also apparent from the face of the study itself, which counted deaths for *any reason, any time* in the eight years following an abortion.[120] As Dr. Coleman, one of the co-authors later

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[114] Dorothy A. Fink et al., *Trends in Maternal Mortality and Severe Maternal Morbidity During Delivery-Related Hospitalizations in the United States, 2008 to 2021*, 6 JAMA Network Open 1 (2023).

[115] The CLI Comment Letter cites Skop I. Fact Check: *Abortion is 14 Times Safer than Childbirth*, Charlotte Lozier Institute, published April 25, 2024, accessed July 23, 2025 https://lozierinstitute.org/fact-check-abortion-is-14-times-safer-than-childbirth/, which in turn relies upon Gissler M, Hemminki E, Lönnqvist J, *Suicides After Pregnancy in Finland, 1987-94: Register Linkage Study*, 313 BMJ 1431-1434 (Dec. 7, 1996); Gissler M, Kauppila R, Meriläinen J, Toukomaa H, Hemminki E, *Pregnancy-Associated Deaths in Finland 1987-1994–Definition Problems and Benefits of Record Linkage*, 76 Acta Obstet. Gynecol. Scand., 651-657 (1997); Gissler M, Berg C, Bouvier-Colle MH, Buekens P, *Injury Deaths, Suicides and Homicides Associated with Pregnancy, Finland 1987-2000*, 15 Eur. J. Public Health 459-463 (2005).

[116] Dep. of Ingrid Skop, MD at 152:20-153:4, 153:13-19, *Planned Parenthood Ass'n of Utah v. Miner*, No. 2:19-cv-00238 (D. Utah Sept. 2, 2020), Dkt. #81-1 at 60-62 (Skop Utah Dep.).

[117] *Id.* at 153:20:22, 158:17-159:5.

[118] *Id.* at 158:17-159:19.

[119] Dep. of Priscilla Coleman, PhD, at 243:6-244:6, *Planned Parenthood Ass'n of Utah v. Miner*, No. 2:19-cv-00238 (D. Utah Sept. 16, 2020), Dkt. #81-1 at 793-794 (Coleman Utah Dep.).

[120] David C. Reardon et al., *Deaths Associated With Pregnancy Outcome: A Record Linkage Study of Low Income Women*, 95 S. Med. J. 834, 836 (Aug. 2002) (cited at n.18 in Skop I. Fact Check: *Abortion is 14 Times Safer than Childbirth*, *supra* n.115); *see also infra* n.162 (discussing David Reardon).

testified, if a woman "got hit by a car five years after her abortion and died" or was "randomly robbed in a parking lot five years after her abortion and shot and killed," both of those would be counted as an abortion-associated death in the study.[121] All of these flaws demonstrate the inherent unreliability of CLI's statistic.

Further, more recent and reliable studies confirm that "[l]egal induced abortion is markedly safer than childbirth,"[122] that "women receiving wanted abortions had similar or better mental health outcomes than those who were denied a wanted abortion,"[123] and that "[l]evels of suicidal ideation were similarly low between women who had abortions and women who were denied abortions."[124] Further, the theory that abortion causes mental health harm has been debunked by leading national and global authorities—including the nonpartisan National Academies of Science, Engineering, and Medicine (National Academies), the American Psychological Association (APA), and the United Kingdom's Royal College of Psychiatrists (Royal College)—following exhaustive scientific reviews.[125]

Third, CLI argues that many patients have contraindications to mifepristone and that removal of the REMS increases their risk, especially for patients who might be suffering an ectopic pregnancy. But mifepristone's contraindications and precautions are set forth on the medication's label, ensuring that prescribers are aware of them.[126] And as the recent citizen

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[121] Coleman Utah Dep. at 246:7-23.

[122] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstet. Gynecol. 215, 216 (Feb. 2021) (putting the risk of death associated with childbirth at approximately 14 times higher than that with abortion), AGO-PET00963. *See also* Ex. 1 at n.42 (explaining how that study evaluated data from 1998-2005 and that since that time, the risk of death during childbirth has more than doubled and the risk of death during a legal abortion has further decreased).

[123] M. Antonia Biggs et al., *Women's Mental Health and Well-being Five Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study*, 74 JAMA Psychiatry 169, 177 (Feb. 2017); *see also* D.G. Foster et al., *A Comparison of Depression and Anxiety Symptom Trajectories Between Women Who had an Abortion and Women Denied One*, 45 Psychol. Med. 2073-82 (July 2015) (concluding that women who received an abortion had similar or lower levels of depression and anxiety than women denied an abortion).

[124] M. Antonia Biggs et al., *Five-Year Suicidal Ideation Trajectories Among Women Receiving or Being Denied an Abortion*, 175 Am. J. Psychiatry 345 (Sept. 1, 2018) (finding that levels of suicidal ideation were similarly low between women who had abortions and women who were denied abortions).

[125] *See* Brenda Major et al., *Report of the APA Task Force on Mental Health and Abortion*, Am. Psych. Ass'n, (2008), https://www.apa.org/pi/women/programs/abortion/mental-health.pdf; Brenda Major et al., *Abortion and Mental Health: Evaluating the Evidence*, 64 Am. Psych. 863 (2009) (update to APA Task Force Report 2008); Nat'l Acads. of Science, Eng'g & Med., *The Safety and Quality of Abortion Care in the United States* 100 (2018), AGO_PET02360-282; Nat'l Collaborating Ctr. for Mental Health (NCCMH), Acad. of Med. Royal Colls., *Induced Abortion and Mental Health: A Systematic Review of the Mental Health Outcomes of Induced Abortion, Including Their Prevalence and Associated Factors* (2011), https://www.aomrc.org.uk/wp-content/uploads/2024/06/Induced_Abortion_Mental_Health_1211.pdf; Position Statement on Abortion and Women's Reproductive Health Care Rights, Am. Psychiatric Ass'n (2020), https://www.psychiatry.org/getattachment/08e82a63-3faa-4e43-bf2f-f459aca9c47e/Position-Abortion-Family-Planning.pdf.

[126] FDA, *Mifepristone 2023 Labeling and Medication Guide* 16 (2023), AGO-PET01178-1196; *see also* Committee on Practice Bulletins—Gynecology and the Society of Family Planning, *Practice Bulletin 225,*

petition filed by the American College of Obstetricians and Gynecologists (ACOG) and other healthcare organizations explains, telehealth protocols for medication abortion offer the same patient protections as in-person dispensing and provide an equivalent level of patient care.[127] Just as would happen during in-person care, patients are evaluated by a clinician who screens the patient to confirm pregnancy (relying on, e.g., medical history, self-reported symptoms, and results of an at-home pregnancy test), assesses the duration of pregnancy, and identifies contraindications such as a potential ectopic pregnancy or other medical conditions or drug allergies.[128] Under these protocols, the patient is advised to obtain in-person testing before proceeding where clinically appropriate, such as when a patient has "significant symptoms of or risk factors for ectopic pregnancy; recent vaginal bleeding or pelvic pain, prior permanent contraception, prior ectopic pregnancy, or intrauterine device in place at conception."[129]

While CLI contends that a telemedicine visit is more dangerous than an in-person visit because a provider is unable to perform an ultrasound,[130] as explained above, a patient will be advised to be seen in-person if they are at risk for an ectopic pregnancy. And if a patient is not at risk for an ectopic pregnancy, an in-person visit does not mean that an ultrasound will be performed. As the Practice Bulletin on *Medication Abortion Up to 70 Days of Gestation*—which CLI relies on in their comment letter (at p. 6)—explains: "For patients with regular menstrual cycles, a certain last menstrual period within the prior 56 days, and no signs, symptoms, or risk factors for ectopic pregnancy, a clinical examination or ultrasound examination is not necessary before medication abortion."[131] Nor has FDA ever required ultrasound. As FDA previously explained, "[w]e determined that it was inappropriate for us to mandate how providers clinically assess women for duration of pregnancy and for ectopic pregnancy"; instead, "[t]hese decisions should be left to the professional judgment of each provider."[132]

Further, as explained in the Mifepristone Multistate Citizen Petition, recent studies confirm that mifepristone's safety record has not changed even as regulatory restrictions have eased.[133] For instance, one peer-reviewed published study, which included 6,034 U.S. patients

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Medication Abortion Up to 70 Days of Gestation, 136 Obstetrics & Gynecology e31, e38 (Oct. 2020) (discussing eligibility and contraindications; explaining that "most patients at 70 days of gestation or less who desire abortion are eligible for a medication abortion" and "[t]here are medical conditions for which a medication abortion may be preferable to uterine aspiration"), AGO-PET00323.

[127] Citizen Petition from Sandra E. Brooks, Chief Exec. Officer, Am. Coll. of Obstetricians & Gynecologists, et al. to FDA (Jan. 31, 2025), AGO-PET00261.

[128] *Id.* (citing Elizabeth G. Raymond et al., *Commentary: No-Test Medication Abortion: A Sample Protocol Increasing Access During a Pandemic and Beyond*, 101 Contraception 361, 362 (2020)).

[129] *Id.*

[130] CLI Comment Letter at 7.

[131] Committee on Practice Bulletins—Gynecology and the Society of Family Planning, *Practice Bulletin 225, Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology e31, e38 (Oct. 2020), AGO-PET00324.

[132] FDA, Response to Docket No. FDA-2002-P-0364 at 18 (Mar. 29, 2016).

[133] Ex. 1 at 12-16; *supra* n.104.

who obtained medication abortion via telehealth in twenty states from April 2021 to January 2022, found an overall effectiveness rate of 97.7% and an overall safety rate of 99.7%.[134] The study further found that "[t]he serious adverse event rate of 0.25% and ectopic pregnancy rate of 0.14% were also similar to previous studies of in-person medication abortion care, which found adverse event rates of 0.2–0.5%, and ectopic pregnancy rates of 0.2%," and that "[b]oth effectiveness and safety rates were similar to the rates for medication abortions with in-person screening tests as published on the FDA label."[135] Other studies have come to similar conclusions on the safety of mifepristone using telemedicine.[136] And these conclusions are further corroborated by the declarations of the departments of health of several of Petitioner States similarly attesting to the safety of medication abortion by telemedicine in their states.[137]

CLI also feigns concern about a purported "fourfold increased complications from medical compared to surgical abortions."[138] But this statement is highly misleading. Both studies that CLI cites for this point (in n.21) conclude that the risk of serious adverse events from mifepristone is very low. The 2009 Niinimaki study,[139] for instance, was conducted in Finland, where "any return visit to the health facility, even for additional consultation, is categorized as a complication."[140] Thus, many of the "complications" reported were only "consultations" for concerns that brought women back to the health care system.[141] Indeed, one of the study's co-authors specifically objected to the study being cited for the proposition of medication abortion having a "fourfold higher" rate of adverse events, explaining that the study was being "purposely misunderst[ood]" and that adverse events were being "overemphasiz[ed]" "despite overwhelming scientific evidence of the drug's safety and the study itself noting the rarity of serious complications."[142] He characterized misuse of his study as a "political game [that] has nothing to do with the scientific process."[143] While the 2015 Upadhyay study found that there were more complications for medication abortion than surgical abortions, the study also explained that "vast majority" of complications were "minor," and that the rate "may be overestimated with aspirations performed presumptively or to alleviate bleeding or cramping

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[134] Ushma Upadhyay et al., *Effectiveness and Safety of Telehealth Medication Abortion in the United States*, 30 Nature Med. 1191, 1192, 1193, 1196 (2024), AGO-PET03433-3435, AGO-PET003438.

[135] *Id.* at 1194, AGO-PET03436.

[136] *Supra* n.104.

[137] *See supra* 6-10 & n.101.

[138] CLI Comment Letter at 6.

[139] Maarit Niinimäki et al., *Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 114 Obstet. Gynecol. 795 (Oct. 2009).

[140] Mary Fjerstad et. al, *To the Editor: Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 115 Obstet. Gynecol. 660 (Mar. 2010).

[141] Maarit Niinimäki et al., *In Reply: Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 115 Obstetrics & Gynecology 660 (Mar. 2010).

[142] Lauren Weber et al., *Unpacking the Flawed Science Cited in the Texas Abortion Pill Ruling*, Wash. Post (Apr. 13, 2023), https://perma.cc/3HPD-VWBH.

[143] *Id.*

symptoms."[144] The study further found that the rate of *major* complications was incredibly low for both types of abortion, with a major complication rate of 0.31 for medication abortion and 0.16 for first-trimester aspiration.[145]

Fourth, while ignoring the overwhelming weight of scientific evidence and 25 years of medical practice of safe prescribing of mifepristone to women in the United States, CLI attempts to poke holes in a handful of studies cited in the Mifepristone Multistate Citizen Petition arguing that the petition "lacks key context for assertions made regarding mifepristone's safety."[146] But as major medical organizations told the U.S. Supreme Court last year, "mifepristone has been discussed in more than 780 medical reviews and used in more than 630 published clinical trials—of which more than 420 were randomized controlled studies, the gold standard in research design."[147] And these hundreds of studies—consistent with the data maintained by departments of health in many of Petitioner States—have overwhelmingly found serious adverse events to be extremely rare.[148]

Against this overwhelming backdrop of high-quality scientific evidence supporting mifepristone's safety, CLI seeks to have FDA rely on a small group of studies authored by a handful of anti-abortion stakeholders whose publications and testimony on abortion safety have been retracted by journals and discredited by courts.[149] Chief among those is the recently-released self-published paper by EPPC,[150] which, as discussed above, has been widely rejected as biased and scientifically flawed, including by abortion opponents.[151]

CLI's Comment also relies extensively on the publications of Dr. Ingrid Skop.[152] But as noted above, in 2022, a court rejected Dr. Skop's testimony on the risks of abortion complications and quality of abortion care, finding that "Dr. Skop has no experience in performing abortions; admitted that her testimony on the risks of certain abortion complications was inaccurate and overstated, or based on data from decades ago; admitted that her views on abortion safety are out of step with mainstream, medical organizations; and provided no credible

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[144] Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstet. Gynecol. 175, 182 (2015), AGO-PET03460.

[145] *Id.* at 178, AGO-PET03456.

[146] CLI Comment Letter at 7.

[147] Br. of American College of Obstetricians and Gynecologists, American Medical Association, Society for Maternal-Fetal Medicine, and Other Medical and Public Health Societies as Amici Curiae in Supp. of Pet'rs at 9 & n.10, *FDA v. All. for Hippocratic Med.*, Nos. 23-235 & 23-236 (U.S. Oct. 12, 2023) (basing numbers on a review of PubMed, the National Institute of Health's sponsored database of research studies).

[148] *Id.*; *supra* at 5-10, n.104; *see* Ex. 1 at 12-16.

[149] *Supra* n.92; *infra* nn.153, 157.

[150] Jamie Bryan Hall & Ryan T. Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event* 1 (2025), AGO-PET01539.

[151] *Supra* at 10-11; Ex. 1 at 16-21, 39-41; *see also* Kimberly Heatherington, *Experts Flag Concerns over EPPC Study on Dangers of Pill Used in Miscarriage Care, Abortion*, Catholic Review (May 21, 2025).

[152] *See* CLI Comment Letter nn.1, 14, 15, 17, 18, 19, 20, 23, 26, 27.

scientific basis for her disagreement with recognized high-level medical organizations in the United States."[153] She also previously admitted in a deposition as recently as 2020 that she is "not a really good researcher,"[154] and that she cited the website abort73.com for statistics in an expert report because she did not find another data source, even though she didn't know "who created the website" or "who supplies the numbers," because she thought the statistics were "probably fairly accurate."[155]

CLI's reliance on studies by Dr. Donna Harrison are similarly misplaced.[156] Her testimony on abortion has been discredited by courts across the country, which have found her expert opinions inaccurate, unsupported by research, and distorted to serve her ideological goals.[157] And although she is an obstetrician-gynecologist, she has not practiced medicine since 2000, the year mifepristone was first approved.[158] Other CLI-affiliated authors have similarly had their research questioned or retracted.[159]

In short, CLI's small number of self-serving studies generated by a handful of unreliable authors fail to overcome the legion of peer-reviewed studies and decades of patient data supporting mifepristone's safety and efficacy over the last 25 years.

Finally, as discussed in the Mifepristone Multistate Citizen Petition, arguments regarding reproductive coercion are not a basis for maintaining the Mifepristone REMS Program.[160] While CLI cites two studies concerning women being coerced to have abortions,[161] the Mifepristone

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[153] *Planned Parenthood of Sw. & Cent. Fla. v. State* (*PPSCF*), No. 2022 CA 912, 2022 WL 2436704, at *13 (Fla. Cir. Ct. July 5, 2022), *rev'd on other grounds*, 344 So. 3d 637 (Fla. Dist. Ct. App. 2022), *pet. for review granted*, Nos. SC2022-1127, SC2022-1050 (Fla. Jan. 23, 2023).

[154] Skop Utah Dep. at 120:25–121:7, 121:5-7, 123:1-9.

[155] *Id.* at 120:9-123:2.

[156] *See* CLI Comment Letter nn.1, 7, 9, 24.

[157] *See, e.g.*, *Little Rock Fam. Plan. Servs. v. Rutledge*, 397 F. Supp. 3d 1213, 1268, 1273, 1282 (E.D. Ark. 2019) (finding that the articles Dr. Harrison cited in her declaration "d[id] not support" her assertions), *aff'd in part*, *vacated in part*, 984 F.3d 682 (8th Cir. 2021), *vacated and remanded*, 142 S. Ct. 2894 (2022); *Planned Parenthood Ark. & E. Okla. v. Jegley*, No. 4:15-cv-00784, 2018 WL 3029104, at *42 (E.D. Ark. June 18, 2018) (rejecting Dr. Harrison's testimony on complications of medication abortion as "inaccurate and incomplete"); *Planned Parenthood Ark. & E. Okla. v. Jegley*, No. 4:15-cv-00784, 2016 WL 6211310, at *22 (E.D. Ark. Mar. 14, 2016) (discussing Dr. Harrison's affivadit and explaining that the "studies [she] cite[d], for a variety of reasons, d[id] not support her position"), *vacated and remanded on other grounds*, 864 F.3d 953 (8th Cir. 2017); *MKB Mgmt. Corp. v. Burdick*, 855 N.W.2d 31, 68 (Oct. 28, 2014) ("Dr. Harrison's opinions have shifted dramatically over time, and appear to be shaped primarily by the position she is advocating at the moment."); *id.* ("[Her opinions] lack scientific support, tend to be based on unsubstantiated concerns, and are generally at odds with solid medical evidence. To the extent she referenced published studies during her testimony, Dr. Harrison tended to present the results in an exaggerated or distorted manner.").

[158] *Little Rock*, 397 F. Supp. 3d at n.25.

[159] *See supra* n.92.

[160] Ex. 1 at 37-38.

[161] David C. Reardon & Tessa Longbons, *Effects of Pressure to Abort on Women's Emotional Responses and Mental Health*, 15 Cureus 1 (Jan. 2023), AGO-PET00867-846; David C. Reardon et al., *The Effects of Abortion*

Multistate Citizen Petition addresses the numerous flaws of these studies.[162] Further, CLI ignores the broad landscape of reproductive coercion, which also includes birth control sabotage and forced pregnancies by abusive partners.[163] Indeed, advocates for survivors of intimate partner violence (IPV), filed a comment in support of ACOG's citizen petition seeking removal of the Mifepristone REMS Program, explaining how restricting access to mifepristone will cause particularly grave harm to IPV survivors by limiting their ability to access abortion care, thus increasing their risk of health complications, violence, and homicide.[164] As they explain in their comment, "[m]eaningful access to abortion care, while important to all women, is particularly critical for IPV survivors, and especially those whose unintended pregnancies resulted from reproductive coercion or rape"; "[m]ifepristone provides a safe and private abortion option for many people, such that maintaining access to mifepristone is critical for survivors of IPV."[165] Indeed, "[t]he ability to access mifepristone through telehealth services and mail delivery plays a crucial role in providing a safe and private abortion option" and "is particularly important for survivors who cannot safely visit clinics due to the controlling nature of their partners."[166] If FDA determines it is within its purview to consider the issue of coercion in making a REMS modification decision, it should meaningfully grapple with the importance of increasing access to mifepristone for IPV survivors.[167]

III. The Mifepristone REMS Program Unduly Burdens Patient Access Without Improving Patient Safety in Petitioner States

Notwithstanding that medication abortion has proven to be incredibly safe for patients in Petitioner States, the Mifepristone REMS Program unduly burdens patient access and the

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Decision Rightness and Decision Type on Women's Satisfaction and Mental Health, 15 Cureus 1 (May 2023), AGO-PET00877-887.

[162] Ex. 1 at 245. In addition, both studies were co-authored by Dr. David C. Reardon, whose work has been discredited by even his long-time collaborator Dr. Priscilla Coleman (discussed above), who admitted under oath that Dr. Reardon is "not good at statistics" and is "too political." *Adams & Boyle, P.C. v. Slatery*, (M.D. Tenn. No. 3:15-cv-0705, Dkt. #221, Tr. Proceedings Vol. 3-A at 88:1-17 (Sept. 25, 2019).

[163] *See* Karen Trister Grace & Jocelyn C. Anderson, *Reproductive Coercion: A Systematic Review*, 19 Trauma, Violence, & Abuse 371, 372, 379 (2018), AGO-PET01625-1658 (explaining that "[r]eproductive coercion is behavior that interferes with the autonomous decision-making of a woman, with regard to reproductive health" and "may take the form of birth control sabotage, pregnancy coercion, or controlling the outcome of a pregnancy").

[164] Legal Voice Comment Letter on Citizen Petition; American College of; Obstetricians and Gynecologists; Society of Family Planning; Society for Maternal-Fetal Medicine Request that FDA remove the Mifepristone Shared System REMS Program (April 11, 2025), https://www.regulations.gov/comment/FDA-2025-P-0377-0013.

[165] *Id.* at 4.

[166] *Id.* at 5; *see also* Cantrell Decl. ¶ 12 ("Medication abortion offers greater privacy for patients, some of whom may fear being seen by community members or by an abuser if forced to visit a known abortion clinic.").

[167] *See* Legal Voice Comment Letter on Citizen Petition; American College of; Obstetricians and Gynecologists; Society of Family Planning; Society for Maternal-Fetal Medicine Request that FDA remove the Mifepristone Shared System REMS Program at 5-6 (April 11, 2025), https://www.regulations.gov/comment/FDA-2025-P-0377-0013.

healthcare delivery system in contravention of federal law. Under the Food, Drug, and Cosmetic Act, ETASU may be imposed only where "required . . . to mitigate a specific serious risk" of a "serious adverse drug experience," and only where the risk is sufficiently severe that FDA would not approve, or would withdraw approval of, the medication, absent ETASU. 21 U.S.C. § 355-1(f)(1)(A). Further, ETASU must not be "unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas," and must "minimize the burden on the health care delivery system." *Id.* §§ 355-1(f)(2)(C)-(D).

As explained in the Mifepristone Multistate Citizen Petition, the current regulatory requirements for prescribing and dispensing mifepristone—requiring patients to sign an agreement form and providers and pharmacies to obtain special certification—are unrelated to any "specific risk" of the drug, let alone required to mitigate any perceived risk. Ex. 1 at 21-22. Nevertheless, by limiting distribution of mifepristone through the Mifepristone REMS Program, the mifepristone ETASU unduly burdens patients and the healthcare delivery system in contravention of federal law. While these burdens are discussed extensively in the Mifepristone Multistate Citizen Petition, *see* Ex. 1 at 21-38, a recent article in the Journal of the American Medical Association (JAMA) that post-dates the Mifepristone Multistate Citizen Petition provides further evidence about these unwarranted burdens.[168]

First, with regards to the Prescriber Certification ETASU, the article explains that "prescriber certification is a meaningless self-certification process requiring attestation of fundamental skills of any clinician caring for patients in early pregnancy" and that "[i]nstead of benefiting patients," it acts as a "barrier to provision" by discouraging nearly 1 in 10 obstetrician-gynecologists from providing medication abortion.[169] It explains that "[c]linicians may be concerned that signing the form could identify them as an abortion provider if that information became publicly available," and that the certification form "[r]educes the pool of abortion providers when abortion access is already limited."[170] The article also highlights how FDA's retention of the Prescriber Certification ETASU for mifepristone contrasts with FDA's treatment of other medications that have had similar REMS removed, specifically flibanserin (Addyi) and tenofovir/emtricitabine (TDF/FTC; Truvada).[171]

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[168] Daniel Grossman, MD & Erica Chung, BA, *Evidence Supports Removing Restrictions on Mifepristone*, 334 JAMA 205-206 (June 12, 2025)

[169] *Id.*; *see* Grossman D, Grindlay K, Altshuler AL, Schulkin J., *Induced Abortion Provision Among a National Sample of Obstetrician-Gynecologists*, 133 Obstet & Gynecol. 477-483 (Mar. 2019) (study finding that 9% of obstetrician-gynecologists who did not provide medication abortion but had patients seeking abortion reported that the form requirement was a reason they did not offer the service), AGO-PET00835.

[170] Daniel Grossman, MD & Erica Chung, BA, *Evidence Supports Removing Restrictions on Mifepristone*, 334 JAMA at 206 (Table) (June 12, 2025).

[171] *Id.* ("Studies demonstrated the safety of flibanserin, leading the FDA to remove REMS requirement that prescribers agree to counsel patients about the potential risk of hypotension and syncope"; "FDA removed prescriber education and training materials for TDF/FTC after acknowledging that the majority of clinicians were aware of HIV prevention methods).

Second, the article explains how the Patient Agreement form ETASU "duplicates information in consent forms and the Medication Guide and includes wording that could be confusing for patients."[172] For instance, if the medication is used off label for miscarriage management consistent with evidence-based practice, the "form's wording may cause confusion" by requiring the patient to agree that she had voluntarily terminated the pregnancy.[173] Further, because "the Medication Guide would still be provided to patients as part of the drug's labeling," removing the Patient Agreement form would not reduce the overall amount of information provided to patients.[174]

Third, while the article acknowledges that "little research has documented the barriers to pharmacy certification," the "excessive" list of FDA requirements of certified pharmacies likely poses a barrier given that "[e]ven in states with protective abortion legislation . . . pharmacies have been slow to start dispensing mifepristone."[175] Further, the article points to FDA's treatment of flibanserin, for which FDA removed the pharmacy certification requirement given the evidence of the medication's safety, as further reason for removing the Pharmacy Certification ETASU.[176]

Fourth, the article emphasizes that "complete removal of the REMS for mifepristone would be consistent with the changes made to flibanserin and TDF/FTC and supported by extensive evidence of the low prevalence of serious adverse events and abundant information available for patients and clinicians."[177] The article cites the record in Canada and discusses how adverse events and complications have remained stable after Canada removed its REMS-like restrictions in 2017, and how "allowing it to be dispensed like any other prescription medication" has improved access to abortion care in Canada.[178] This article is simply the latest in the medical community's consistent, science-backed calls for removal of the Mifepristone REMS Program over the last decade.[179]

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[172] *Id.* at 205.

[173] *Id.* at 206 (Table) (citing Schreiber CA, Creinin MD, Atrio J, et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 New Engl. J. Med. 2161-2170 (June 7, 2018), AGO-PET00343-352).

[174] Daniel Grossman, MD & Erica Chung, BA, *Evidence Supports Removing Restrictions on Mifepristone*, 334 JAMA at 206 (Table) (June 12, 2025).

[175] *Id.* at 205 (citing Beshar I, Miller HE, Kruger S, Henkel A., *Mifepristone and Misoprostol in California Pharmacies After Modifications to the Risk Evaluation and Mitigation Strategy Program*, 137 Contraception 1-3 (2024).

[176] Daniel Grossman, MD & Erica Chung, BA, *Evidence Supports Removing Restrictions on Mifepristone*, 334 JAMA at 206 (Table) (June 12, 2025).

[177] *Id.* at 205-206; *see also* Ex. 1 at 38-41 (discussing medications with other similar or more serious risks than mifepristone that are not under a REMS).

[178] *Id.* at 206; *see also* Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 New Engl. J. Med. 57, 57 (2022), AGO-PET01770-1780.

[179] *See, e.g.*, Mifeprex REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 NEJM 790, 791, AGO-PET02216-2220 (Feb. 23, 2017); Jane E. Henney & Helene D. Gayle, *Time to Reevaluate U.S. Mifepristone Restrictions*, 381 NEJM 597, 597, AGO-PET01551 (Aug. 15, 2019) (acknowledgment

Evidence from Petitioner States confirms these burdens. In its recent litigation with FDA, the Petitioner States submitted evidence on the burdens the Mifepristone REMS Program imposes on their states. While this evidence was not part of the administrative record and therefore was not previously considered by FDA in conjunction with the Mifepristone REMS Program, the Multistate Citizen Petition asked FDA to consider the testimony submitted in *Washington v. FDA*, No. 1:23-cv-03026 (E.D. Wash.) as part of its current mifepristone review.[180] Petitioner States, who collected that evidence, now reiterate that request and highlight the following testimony for FDA's consideration:

- Forcing patients to go to "specially certified" providers, as opposed to their primary care or family physicians, can require patients to travel long distances, disrupts continuity of care, stigmatizes routine health care, and discourages patients from making the best health care choices for themselves and their families.[181] It likewise discourages family medicine doctors and generalist obstetrician-gynecologists from prescribing mifepristone.[182] As one physician explained, "REMS are generally only placed on dangerous drugs like opioids and the existence of the REMS, coupled with the provider certification, creates a disincentive to prescribe a very safe medication."[183] These harms, in turn, will be felt most intensely by patients in rural or medically underserved areas with an already limited number of medical providers.[184]

- The Prescriber Agreement Form ETASU is unnecessary because medical providers qualified to provide medication abortion already possess the skills that providers must attest to in the form.[185] As one Washington provider testified: "Any provider who might

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by former FDA Commissioner Henney that "[t[he accumulated knowledge about mifepristone strongly suggests that the current restricted distribution system is not aligned with the limited risks that are now known to be posed by the drug"); *Improving Access to Mifepristone for Reproductive Health Indications – Position Statement*, Am. Coll. Obstetricians & Gynecologists (June 2018, reaff'd March 2021), AGO-PET01460-1462; Congress of Delegates, Am. Acad. Of Fam. Physicians, *Resolution No. 506 (Co-Sponsored C) – Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on Mifepristone* (May 24, 2018), AGO-PET00339-342.

[180] *See also* Ex. 1 at 2 n.3.

[181] Janiak Decl. ¶¶ 24-26; Godfrey Decl. ¶¶ 15-17, 19, 21, 24-25 28-32, AGO-PET00991-995, AGO-PET0997-998, AGO-PET01000, AGO-PET01003-1004 ; Lazarus Decl. ¶ 16; Colwill Decl. ¶¶ 24-25; Shih Decl. ¶¶ 20-29, AGO-PET01324-1330; Prager Decl. ¶¶ 37–40, AGO-PET03289-91; Henry Decl. ¶¶ 5-6; Gold Decl. ¶ 21; Schreiber Decl. ¶ 75.

[182] Godfrey Decl. ¶¶ 15-27, AGO-PET00991-1005; Janiak Decl. ¶¶ 14-16; Shih Decl. ¶¶ 20-28, AGO-PET01324-1329; *see also* Schreiber Decl., ¶ 74.

[183] Prager Decl. ¶ 37, AGO-PET03290.

[184] Godfrey Decl. ¶ 32, AGO-PET01008; Janiak Decl. ¶ 26; *see also* Henry Decl. ¶¶ 7-8 (noting the limited availability of reproductive healthcare providers in rural Washington and explaining that "the requirements imposed by the [mifepristone] REMS act to further limit access to comprehensive reproductive health care services to patients in this community").

[185] Colwill Decl. ¶ 26; Gold Decl. ¶ 20; Nichols Decl. ¶ 26, AGO-PET01928; Prager Decl. ¶ 29, AGO-PET03286.

provide a medication abortion—including obstetricians, gynecologists, family physicians, primary care physicians, and certified nurse midwives—are already extensively trained in pregnancy dating, ectopic risk factors, and care coordination. The provider certification thus does not provide any additional patient safety."[186]

- While not adding to patient safety, the Prescriber Certification ETASU discourages qualified providers from providing medication abortion due to the serious and well-founded concerns about creating a documented association with abortion care, particularly given the growing criminalization and penalization of abortion following the *Dobbs* decision.[187] As one Pennsylvania doctor explained, "I have also had many one-on-one conversations with physicians who would like to implement mifepristone in their gynecological practices, but are concerned that by completing the prescriber agreement, they might enable anti-abortion activists to access their information and target them for harassment or worse."[188] Another physician explained that "[t]hese fears are particularly acute for doctors who hold medical licenses in multiple states" and for medical residents "who come from states where abortion is now illegal and who plan to eventually practice medicine in those states."[189] These fears are well-founded. Indeed, one physician testified to having her name, picture, medical licenses, and address listed on a website of an organization targeting abortion providers.[190]

- The Patient Agreement Form harms the patient experience and makes patient counseling more difficult because it suggests mifepristone is unsafe, when it is not, and may contain information that is not clinically relevant to a patient.[191] As one Pennsylvania doctor

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[186] *Id.*; *see also* Schreiber Decl. ¶¶ 49, 51-58 ("[C]linicians are already governed by strict clinical, ethical, and legal standards, such as licensure requirements and scope of practice statutes, that direct the safe prescription and dispensing of any and all prescription drugs. It is a basic tenet of medical ethics and the regulation of clinical care that clinicians may prescribe a drug only if they have the skills to properly and safely do so, and only if they can ensure appropriate surveillance as needed. For example, the ACOG Code of Professional Ethics dictates that 'the obstetrician-gynecologist should recognize the boundaries of his or her particular competencies and expertise and must provide only those services and use only those techniques for which he or she is qualified by education, training, and experience.' All clinicians are bound by analogous requirements, and any who fail to adhere to those ethical and legal standards risk license investigation and revocation by state licensure boards as well as medical malpractice liability.").

[187] Godfrey Decl. ¶ 27, AGO-PET01004-1005; Gold Decl. ¶¶ 17-19; Janiak Decl. ¶ 20; Shih Decl. ¶¶ 23-26, AGO-PET01327-1328; Prager Decl. ¶¶ 38-40, AGO-PET03290-3291; Schreiber Decl. ¶¶ 59-61, 63; *see also* Dillon Decl. ¶¶ 24-33 (discussing threats to abortion providers); Cantrell Decl. ¶ 9.

[188] Schrieber Decl. ¶ 60.

[189] Prager Decl. ¶ 39, AGO-PET03291; *see also* Schrieber Decl. ¶ 61.

[190] Shih Decl. ¶ 24, AGO-PET01327.

[191] *See, e.g.*, Godfrey Decl. ¶¶ 12-14, AGO-PET00989-991; Shih Decl. ¶ 14, AGO-PET01321-1322; Lazarus Decl. ¶ 18; Janiak Decl. ¶ 22; Nichols Decl. ¶ 35, AGO-PET01931 (noting that the Patient Agreement Form causes patients "concern" that mifepristone is "inherently risky"); Prager Decl. ¶¶ 18, 31, AGO-PET03282, AGO-PET03287-3288 ("the Patient Agreement Form acts to unnecessarily heighten patient worry and stress"); Colwill Decl. ¶ 27 ("The Patient Agreement Forms required by the REMS can also cause patient confusion and distress").

explains: "The patient agreement form is based on the science that existed in 2016 and does not evolve alongside evidence-based clinical practice. It contains information that may be irrelevant to an individual patient and/or inconsistent with a clinician's practice or preferred counseling. It is understandably confusing for patients, and undermines the clinician-patient relationship, when their provider tells them one thing, but they must then sign an official FDA form saying something different."[192]

- The Patient Agreement Form ETASU can be upsetting for many patients who are prescribed mifepristone for miscarriage management.[193] As one Oregon physician explained, "I have had patients who were already undergoing the traumatizing experience of a miscarriage, become deeply upset, confused, or distressed at having to sign a form about medication abortion" attesting that they are deciding to voluntarily terminate their pregnancy.[194]

- The Patient Agreement Form ETASU also "adds at least 2-3 minutes of required provider time per patient," which adds up to hundreds of hours over the course of the year.[195] Given that many reproductive healthcare providers have long waitlists, this is time that could have been spent providing care to other patients.[196] For telemedicine patients who are unable to e-sign documents, it also imposes an additional burden to care, and may delay or impede their ability to obtain a medication abortion.[197]

- The Pharmacy Certification ETASU also unduly burdens providers by requiring providers to send a prescriber agreement form to *every* certified pharmacy to which they send a mifepristone prescription.[198] This means that a prescriber cannot simply call-in a prescription to a patient's desired pharmacy; instead, the prescriber must research certified pharmacies near the patient and send their prescriber agreement form to the pharmacy before sending the prescription.[199] As one abortion provider in Washington explained, requiring providers "[t]o track which pharmacies are 'certified' or not, and whether clinicians have 'submitted' their form to each potential 'certified' pharmacy is out of the scope of any mainstream clinic or provider."[200]

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[192] Schreiber Decl. ¶¶ 70-71.

[193] Colwill Decl. ¶¶ 34-37; Nichols Decl. ¶ 27, AGO-PET01928-1929; Schreiber Decl. ¶ 73; *see also* Lazarus Decl. ¶ 18.

[194] Colwill Decl. ¶ 35.

[195] *Id.* ¶ 38.

[196] *Id.* ¶ 39 (discussing the administrative burdens associated with this ETASU and estimating that an additional 280 to 420 patients could have been provided care in Oregon in 2021 if this ETASU was eliminated).

[197] Gold Decl. ¶ 22; Reed Decl. ¶¶ 12-14, AGO-PET00128-129; Shih Decl. ¶ 17, AGO-PET01322-1323.

[198] *See, e.g.*, Shih Decl. ¶¶ 23, 27, AGO-PET01327-1329; Godfrey Decl. ¶ 26, AGO-PET01004; Colwill Decl. ¶¶ 19-20.

[199] Shih Decl. ¶ 27, AGO-PET01328-1329.

[200] Godfrey Decl. ¶ 26, AGO-PET01004.

- The Pharmacy Certification ETASU also "present[s] a series of burdens . . . that are stigmatizing, administratively burdensome, confusing, expensive, and legally risky," which will cause many pharmacies to opt out of dispensing mifepristone, particularly "smaller pharmacies, which are . . . more likely to serve rural, minority, or poor communities."[201]

- The Pharmacy Certification ETASU also requires pharmacies that dispense mifepristone to develop a *sui generis* system to track Prescriber Certifications forms confidentially before pharmacies can fill a mifepristone prescription, which is a requirement that is unique to mifepristone alone. As the Petitioner States emphasized in their court filings, they are aware of no other medication that requires individual pharmacies to *independently create* a secure system to verify prescriber certification.[202]

In sum, the Mifepristone REMS Program unduly burdens patient access in a number of significant ways, including by causing a lack of certified providers,[203] a lack of certified pharmacies,[204] an inability of some patients to e-sign the Patient Agreement Form,[205] reluctance or confusion of some patients regarding the Patient Agreement Form,[206] lagging REMS paperwork delaying patient access to the medication,[207] or some combination of these

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[201] Downing Decl. ¶¶ 9-17, AGO-PET00904-908; Das Gupta Decl. ¶¶ 5-22, AGO-PET03404-3409; Shih Decl. ¶ 34, AGO-PET01332; Singh Decl. ¶¶ 12-14, AGO-PET00074-76; Janiak Decl. ¶ 23 (describing the Pharmacy Certification ETASU acts as an additional burden on patients and the healthcare system and explaining "there is no evidence that a pharmacy should have to be specially certified to dispense mifepristone and it is irrefutably clear that mifepristone can be safely prescribed through the typical avenues"); Lazarus Decl. ¶ 17 (discussing additional burden this ETASU imposes on patients who "do not own a care, do not speak English or have work schedules or family obligations that do not allow them to spend time during the day searching for a specially certified pharmacy"); *see also* Nelson Decl. ¶ 10 (discussing the growing number of counties without a single pharmacy and its impact on mifepristone availability).

[202] *See Washington v. FDA*, No. 1:23-cv-03026 (E.D. Wash. Mar. 30, 2023), Dkt. Nos. 72 & 72-1 (listing drugs for which a pharmacy certification ETASU is required along with a description for how they work differently from the mifepristone pharmacy certification ETASU). As the Petitioner States explained in the *Washington* litigation, the mifepristone REMS works differently from other drugs where certified pharmacies may generally look up the certified prescriber and/or the enrolled patient in a centralized database, which is maintained by the drug's sponsor, to verify the provider's certification and/or the patient's enrollment in the REMS program. Here, the Mifepristone REMS Program imposes the entire administrative burden solely on each individual certified pharmacy to create its own secure, dynamic system for tracking and storing providers' certification information. *See id.*; *see also* Ex. 1 at 32-26. As the declarations submitted in that litigation by the University of Washington explain, creating that system can be costly and time consuming. *See generally* Das Gupta Decl. ¶¶ 5-22, AGO-PET03404-3409; Singh Decl. ¶¶ 12-22, AGO-PET00074-78; *see also* Downing Decl. ¶¶ 7-17, AGO-PET00904-908.

[203] Godrey Decl. ¶¶ 30-31, AGO-PET01007.

[204] Shih Decl. ¶ 27, AGO-PET01328-1329.

[205] *Id.* ¶ 17, AGO-PET01322-1323.

[206] Prager Decl. ¶ 18, AGO-PET03282.

[207] DasGupta Decl. ¶ 10, AGO-PET03405-3406.

burdens.[208] Given mifepristone's 25-year safety record in Petitioner States, it is time for FDA to remove these burdensome mifepristone REMS with ETASU.

IV. The Petitioner States Have Enacted Laws and Regulations to Ensure the Safety of Medication Abortion in Their States

Like Massachusetts, New York, California, and New Jersey,[209] the Petitioner States have enacted stringent laws and regulations governing the practice of medicine and pharmacy dispensing in their states. Each of the Petitioner States has laws that define the scope and contours of medical practice, oversee medical license requirements for healthcare providers, impose requirements for informed consent, and regulate the prescribing and distribution of prescription medications, which also apply to the provision of medication abortion in the Petitioner States. Indeed, as states where access to abortion is legal and protected, the Petitioner States have incredibly strong motivations to ensure the safe provision of medication abortion within their states.

For the reasons set forth in the Mifepristone Multistate Citizen Petition (Ex. 1 at 41-51), and as set forth more fully below, the goals of the Mifepristone REMS Program's Prescriber Certification, Patient Agreement Form, and Pharmacy Certification requirements are already addressed by state regulations governing the practice of medicine and pharmacies. Specifically, (i) existing state licensure regimes in Petitioner States already require prescribers to certify that they are operating within their scope of practice and meet applicable standards of care within their field; (ii) Petitioner States offer protections for informed consent in their statutes; and (iii) the practice of pharmacy is already regulated by the Petitioner States and encompasses dispensing mifepristone. Ex. 1 at 41-51.[210]

Because the Mifepristone REMS Program does not add to patient safety, and instead unduly burdens access to medication abortion, *see supra* at 22-29 and Ex. 1 at 21-38, FDA should—at minimum—exercise its discretion not to enforce the Mifepristone REMS Program in the Petitioner States. FDA's exercise of enforcement discretion to not enforce the ETASU

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[208] *See* Shih Decl. ¶ 17, AGO-PET01322-1323 ("[D]elaying the process even by a few days may make [some patients] ineligible to select medication abortion."); *see also, e.g.*, Colwill Decl. ¶¶ 18-25; Downing Decl. ¶¶ 9-17, AGO-PET00904-908; Godfrey Decl. ¶¶ 17-20, 27-28, AGO-PET00994-01000, AGO-PET01004-1005; Gold Decl. ¶¶ 15-19, 21, 22, 24, 27; Henry, et al. Decl. ¶¶ 6-8; Janiak Decl. ¶¶ 15-20, 22-23, 26-29; Lazarus Decl. ¶¶ 16-17, 19-20; Nichols Decl. ¶ 38, AGO-PET01932; Prager Decl. ¶¶ 34, 38-41, AGO-PET03288, AGO-PET03290-3292; Shih Decl. ¶¶ 20-27, 29, AGO-PET01324-1330.

[209] *See* Ex. 1 at 41-51.

[210] *See also* Schreiber Decl. ¶¶ 48-58, 67-73 (explaining how clinicians are already governed by strict clinical, ethical, and legal standards, such as licensure requirements and scope of practice statutes, that direct the safe prescription and dispensing of any and all prescription drugs and duplicates informed consent laws and practices).

requirements would help ensure patient access while Petitioner States ensure that providers and pharmacies are compliant with state law that governs their professional conduct.

A. Arizona

Prescriber Certification: Arizona law already achieves what the Prescriber Certification purports to address by requiring that prescribers meet certain qualifications and send the certification to every pharmacy to which they send a prescription. Arizona regulates medical doctors (MDs) through the Arizona Medical Board and doctors of osteopathy (DOs) through the Arizona Osteopathic Board, including licensure requirements, continuing education requirements, and monitoring for statutorily defined unprofessional conduct.[211] Both boards have rigorous oversight, investigatory, and disciplinary authority and are obligated to refer allegations of criminal acts to the relevant criminal enforcement agency.[212]

For example, to ensure patient safety and competent prescription practices, Arizona law guards against "[p]rescribing, dispensing or administering any controlled substance or prescription-only drug for other than accepted therapeutic purposes," as well as "[p]rescribing, dispensing or furnishing a prescription medication or a prescription-only device . . . to a person unless the licensee first conducts a physical or mental health status examination of that person or has previously established a doctor-patient relationship."[213] These standards ensure that prescriptions are based on clinical need and appropriate patient evaluations.

In addition, Arizona has reciprocity regarding disciplinary actions in other jurisdictions, requiring the Medical Board to initiate an investigation "if a medical regulatory board in another jurisdiction in the United States has taken disciplinary action against a licensee for an act that occurred in that jurisdiction that constitutes unprofessional conduct" under Arizona law.[214] Arizona law also already regulates how physicians dispense medication and establishes civil penalties for violations.[215] These laws, and many others, safeguard patient safety and ensure that only competent providers are issuing prescriptions.

Patient Agreement Form: Several Arizona laws protect patients' rights and ensure informed consent in the prescribing context. For example, doctors are subject to discipline for violating privileged communication, failing to inform the patient of the methods used for treatment, or using experimental forms of therapy without adequate informed consent.[216] In

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[211] Ariz. Rev. Stat. §§ 32-1401 *et seq.*, 32-1800 *et seq.*

[212] *Id.* §§ 32-1451(O), 32-1855(J).

[213] *Id.* § 32-1401(27) (defining "unprofessional conduct" regulated by the Arizona Medical Board); *accord id.* § 32-1854(5), (49) (defining "unprofessional conduct" for surgeons and osteopathic physicians).

[214] *Id.* § 32-1451.02.

[215] *Id.* §§ 32-1491, 32-1871; *see also* Ariz. Admin. Code §§ R4-16-301–305, R4-22-301-305.

[216] Ariz. Rev. Stat. § 32-1854(1), (12), (27); *accord* Ariz. Rev. Stat. § 32-1401(27).

addition, doctors face discipline for "[k]nowingly making any false or fraudulent statement, written or oral, in connection with the practice of medicine."[217]

Pharmacy Certification: In light of Arizona laws governing pharmacists, the FDA's proposed Pharmacy Agreement Form and Certification—which mandates that dispensing pharmacies design and implement a system that confidentially tracks prescriber certifications and filled prescriptions—is also unnecessary.

Although Arizona lacks regulations specific to mifepristone, the general statutes and regulations that apply to the practice of pharmacy in Arizona sufficiently ensure that patients receive the right dosage, proper warnings, and other information necessary to safeguard patients.[218] For instance, prescription-only drugs are subject to strict dispensing requirements.[219] Pharmacists must comply with certain record-keeping requirements of prescription orders,[220] and pharmacies must "implement or participate in a continuous quality assurance program to review pharmacy procedures in order to identify methods for addressing pharmacy medication errors."[221]

Further, the Arizona Board of Pharmacy has significant statutory authority to investigate and ensure compliance with law and discipline non-compliance.[222] Pursuant to that authority, the Board has issued regulations regarding general practice standards,[223] requirements for dispensing and refilling prescriptions,[224] and patient counseling.[225] Other relevant regulations include personal registration renewal[226] and continuing education rules.[227]

In addition, both the Arizona Medical Board and Arizona Osteopathic Board require practitioners who dispense controlled substances in an office setting to obtain registrations from their respective boards and to comply with requirements for documentation, packaging, inventory, recordkeeping, and safe storage.[228] Both boards have the authority to conduct investigations and inspections to ensure compliance with these requirements.[229]

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[217] *Id.* § 32-1401(27).
[218] *See generally id.* § 32-1901 et seq.
[219] *Id.* § 32-1968.
[220] *Id.* § 32-1964.
[221] *Id.* § 32-1973(A).
[222] *E.g.*, *id.* § 32-1904.
[223] Ariz. Admin. Code §§ R4-23-402, R4-23-407.
[224] *Id.* § R4-23-402.
[225] *Id.* § R4-23-402(B).
[226] *Id.* § R4-23-202(G).
[227] *Id.* § R4-23-204.
[228] *Id.* §§ R4-16-301-304, R4-22-301-304.
[229] *Id.* §§ R4-16-305, R4-22-305.

B. Colorado

Prescriber Certification: The Prescriber Certification is redundant and unnecessary because the Colorado Medical Board regulates the practice of medicine in Colorado consistent with the Medical Practice Act. The Board regulates physicians' and physician assistants' qualifications for licensure.[230] The Board enforces physician misconduct, specifically failures to meet generally accepted standards, through a detailed disciplinary process.[231] Advanced practice nurses and certified nurse midwives, who could also potentially prescribe mifepristone, are regulated by the Colorado Board of Nursing, including requirements for licensure, practice, and disciplinary process.[232]

Patient Agreement Form: Colorado law protects patients' rights to informed consent to medical care. Informed consent is part of meeting generally accepted standards, which is required by the Practice Act.[233] The Colorado Medical Board has also issued a policy statement advising licensees that the provider-patient relationship requires the provider to "obtain[] appropriate informed consent after any relevant disclosures . . . ."[234] Because Colorado law already achieves what the Patient Agreement Form purports to do, the Patient Agreement Form is unnecessary and duplicative.

Pharmacy Certification: The Pharmacy Agreement Form also imposes an unnecessary burden on Colorado as the Colorado Pharmacy Board licenses pharmacists and registers facilities, pharmacists' authority, and has the power to discipline through a detailed process.[235]

C. Connecticut

Prescriber Certification: In Connecticut, any person who diagnoses or treats any person for any injury, deformity, ailment or disease—including prescribing drugs—without a license may be held criminally liable.[236] Further, individuals may only practice medicine "in the kind or branch of practice stated in such license."[237] The Connecticut Department of Public Health investigates complaints against physicians and the Connecticut Medical Examination Board may discipline a physician's license for, among other things, illegal, incompetent, or negligent practice of medicine or the prescribing of a legend drug, such as mifepristone, without a therapeutic or medically proper purpose.[238] These licensing and disciplinary requirements ensure

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[230] Colo. Rev. Stat. §§ 12-240-110, -113.
[231] *Id.* §§ 12-240-125.
[232] *Id.* §§ 12-255-111, -111.5, -112, -119, -120.
[233] *Id.* §§ 12-240-121(1)(j)
[234] Colorado Medical Board Policy 40-03 (2015).
[235] Colo. Rev. Stat. §§ 12-280-114, -119, -126, -127.
[236] Conn. Gen. Stat. §§ 20-9(a), 20-14, & 53-341(c).
[237] *Id.* § 20-9(a).
[238] *Id.* §§ 20-13b (DPH investigations), 20-13c (discipline by Board).

that only qualified providers can prescribe mifepristone, and only for a proper purpose, making the Prescriber Certification redundant and unnecessary in the state.

Patient Agreement Form: The Patient Agreement Form is also unnecessary as Connecticut already requires informed consent prior to performing an abortion, including providing the patient a thorough explanation of the abortion procedure to be performed and a full description of "the discomforts and risks that may accompany or follow the performance of the procedure."[239] Further, the use of a separate Patient Agreement Form is entirely duplicative because in Connecticut a patient's informed consent for an abortion must be memorialized in a consent form signed by the patient, the counselor who obtains the consent, the physician who will perform the procedure, and an interpreter if one is provided.[240]

Pharmacy Certification: Lastly, the Pharmacy Agreement Form is redundant in Connecticut as statutes and regulations already govern the practice of regulating and dispensing medication. Connecticut prohibits the unlicensed practice of pharmacy and limits the dispensing of legend drugs by pharmacists or prescribing practitioners, who must operate within the scope of their practice.[241] Pharmacists must offer to discuss with the patient the drug being prescribed and offer counseling on the usage of the drug, and must keep records of any counseling provided or refusal of counseling.[242] The Commission of Pharmacy may take disciplinary action—including revocation or suspension of a pharmacist's license—for, among other things, violation of any state statute or regulation related to drugs or the practice of pharmacy or incompetent or negligent work.[243]

D. Delaware

Prescriber Certification: In general, no person may practice medicine in Delaware without a license.[244] In Delaware, physicians and advanced practice clinicians (APC) such as nurse practitioners, certified nurse midwives, and physician assistants, with a collaborative agreement with an appropriately-trained physician, may provide medication and procedural abortion care.[245] These health care providers are subject to regulation of their practice by their respective disciplining authorities.[246] Disciplining authorities have authority to investigate and initiate enforcement actions based on unprofessional conduct by a licensed medical provider.[247]

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[239] Conn. Agencies Regs. § 19-a-116-1(c)(1).
[240] *Id.* § 19-a-116-1(c)(2)
[241] Conn. Gen. Stat. §§ 20-605, 20-613, & 20-571(39).
[242] *Id.* §§ 20-614(d) & (e).
[243] *Id.* § 20-579.
[244] 24 Del. C. § 1720 *et seq*.
[245] 24 Del. C. § 1790.
[246] 24 Del. C. § 1730 *et seq* (Board of Medical Licensure and Discipline); 24 Del. C. § 1922 *et seq*. (Board of Nursing); 24 Del. C. § 1901A *et seq*. (Nurse Multistate Licensure Compact).
[247] 24 Del. C. §§ 1713, 1731, 1909, 1922.

Disciplining authorities can suspend or revoke licenses, limit practice, levy fines, and impose other sanctions on licensees.[248] These protections obviate the need for a Prescriber Certification for mifepristone.

Patient Agreement Form: Delaware law imposes a duty on health care providers to obtain informed consent from patients.[249] Specifically, under Delaware law, "'Informed consent' is a patient's consent to a procedure after the healthcare provider has explained both the nature of the proposed procedure or treatment and the risks and alternatives that a reasonable patient would want to know in deciding whether to undergo the procedure or treatment. The explanation must be reasonably understandable to a general lay audience."[250] To provide informed consent, a healthcare provider must also inform the patient of all material facts related to the treatment.[251] Thus, in the context of medication abortion, an abortion provider in Delaware must explain the nature of the treatment in lay terms and all material facts, including the risks and alternatives, in order to obtain a patient's informed consent. In addition, physicians face discipline for "[t]he use of any false, fraudulent, or forged statement or document or the use of any fraudulent, deceitful, dishonest, or unethical practice in connection with . . . the practice of medicine," or "[a]ny dishonorable, unethical, or other conduct likely to deceive, defraud, or harm the public"[252] and nurse practitioners face discipline if incompetent by reason of negligence or if they any commit unprofessional conduct."[253] The Patient Agreement Form is unnecessary in light of these requirements to obtain informed consent.

Pharmacy Certification: The Board of Pharmacy, a body within Delaware's Department of State, Division of Public Regulation, oversees the practice of pharmacy in Delaware. The primary objective of the Delaware Board of Pharmacy is to promote, preserve, and protect the public health, safety, and welfare. To meet this objective, the Board maintains a registry of drug outlets that manufacture, produce, sell, and distribute drugs, medications, and other materials used to diagnose and prevent illness and disease and to treat injury; monitors the outlets to ensure safe practices; develops standards for professional competency; promulgates rules and regulations; adjudicates complaints against professionals and, when necessary, imposes disciplinary sanctions. Delaware sets strict requirements for pharmacy facilities.[254] When a pharmacist dispenses abortion medication in Delaware, Delaware law requires them to apply a label bearing the name of the prescriber (or prescribing and dispensing health care facility if preferred), complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date.[255] Further, Delaware regulations require

[248] 24 Del. C. §§ 1731, 1922, 1925.
[249] 18 Del. C. § 6852; *Kocher v. Capodanno*, 1990 WL 127823, at *2 (Del. Super. Aug. 31, 1990).
[250] *Spencer v. Goodill*, 2009 WL 4652960, at *2 (Del. Super. Ct. Dec. 4, 2009).
[251] 18 Del. C. § 6852; *Kocher v. Capodanno*, 1990 WL 127823, at *2 (Del. Super. Aug. 31, 1990).
[252] 24 Del. C. § 1731.
[253] 24 Del. C. § 1922.
[254] 24 Del. C. § 2501 *et seq.*
[255] 24 Del. C. § 2522.

that, prior to dispensing a prescriptive medication to a new patient, a pharmacist provide counseling to the patient on pertinent medication information, including concerning "any special directions and precautions for preparation, administration, and use by the patient that the pharmacist determines are necessary" and information about common severe side effects or adverse reactions to a medication.[256] The Board of Pharmacy has broad authority to take disciplinary action against pharmacists for violating any of the foregoing requirements or any other applicable pharmacy law.[257] Imposing an additional certification to dispense mifepristone is unnecessary given these existing protections.

E. District of Columbia

***Prescriber Certification*:** The District of Columbia Board of Medicine regulates the practice of medicine in the District of Columbia. District regulations prohibit licensed physicians from "accept[ing] or perform[ing] professional responsibilities which the licensed physician is not competent to perform."[258] Physicians practicing medicine in the District are also required to "conform to the prevailing standards of acceptable medical practice as determined by the Board or a peer review panel appointed by the Board."[259]

***Patient Agreement Form*:** In the District of Columbia, a physician has a duty to inform the patient of the consequences of a proposed treatment, including any material risks of the treatment.[260] The District of Columbia Court of Appeals has held that "at a minimum, a physician must disclose the nature of the condition, the nature of the proposed treatment, any alternate treatment procedures, and the nature and degree of risks and benefits inherent in undergoing and in abstaining from the proposed treatment."[261]

***Pharmacy Certification*:** The District of Columbia Board of Pharmacy regulates the practice of pharmacy, the practice of pharmaceutical detailing, and the practice of pharmacy technicians.[262] District regulations require pharmacists to exercise sound professional judgment with respect to the accuracy and authenticity of any prescription they dispense.[263] District law also sets out requirements for the proper labeling of prescriptions, including the information to be included on the drug container as required by District and federal law.[264]

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[256] 24 DE Admin. Code 2500-5.2.1.
[257] 24 Del. C. § 2515.
[258] D.C. Mun. Regs. tit. 17, § 4612.5.
[259] *Id.* § 4612.8.
[260] *Crain v. Allison*, 443 A.2d 558, 561 (1982).
[261] *Id.* at 562.
[262] D.C. Code § 3-1202.08(b)(1).
[263] D.C. Mun. Regs. tit. 22-B, § 1300.6; *see also* § 1300.7.
[264] D.C. Code § 47-2885.14.

F. Hawai‘i

Prescriber Certification: Hawai‘i strictly regulates the practice of medicine, which includes the prescription of medications.[265] Individuals are not allowed to practice medicine or hold themselves out as practicing medicine without a valid license from the Hawai‘i Medical Board.[266] Hawai‘i also regulates the practice of telehealth and requires that telehealth services, including a prescription via electronic means, are held to the "same standards of appropriate practice as those in traditional physician-patient settings that do not include [an] in-person visit but which prescribing is appropriate."[267] Hawai‘i telehealth law strictly forbids "issuing a prescription based solely on an online questionnaire" as not "an acceptable standard of care."[268] Advance Practice Registered Nurses with a valid and unencumbered license are also able to prescribe mifepristone if certain conditions are met.[269]

Patient Agreement Form: Hawai‘i already has informed consent laws that protect patients' rights and which would cover abortion care, including use of mifepristone.[270] Under Hawai‘i law, providers are required to provide the patient or their guardian or legal surrogate with relevant information, including: "(1) The condition to be treated; (2) A description of the proposed treatment or procedure; (3) The intended and anticipated results of the proposed treatment or procedure; (4) The recognized alternative treatments or procedures, including the option of not providing these treatments or procedures; (5) The recognized material risks of serious complications or mortality associated with: (A) The proposed treatment or procedure; (B) The recognized alternative treatments or procedures; and (C) Not undergoing any treatment or procedure; and (6) The recognized benefits of the recognized alternative treatments or procedures."[271] In addition, Hawai‘i's insurance code requires that an enrollee have a right to participate in treatment decisions, including treatment options, benefits, risks, and consequences consistent with Hawai‘i's informed consent law.[272]

Pharmacy Certification: Hawai‘i regulates its pharmacists and requires all pharmacists to meet specific qualifications to hold a license.[273] Hawai‘i also requires its pharmacies to keep prescription records of each prescription compounded or dispensed at the pharmacy for a period of not less than five years.[274]

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[265] *See* Haw. Rev. Stat. § 453-1.
[266] *See* Haw. Rev. Stat. § 453-2.
[267] Haw. Rev. Stat. § 453-1.3(c).
[268] *Id.*
[269] *See* Haw. Rev. Stat. § 457-8.7.
[270] *See* Haw. Rev. Stat. § 671-3.
[271] *Id.*
[272] *See* Haw. Rev. Stat. § 432E-4.
[273] *See* Haw. Rev. Stat. §§ 461-5 and 6.
[274] *See* Haw. Rev. Stat. §4 61-13; *see also* Haw. Admin. Rules §§16-95-93 through 95.

G. Illinois

Prescriber Certification: Illinois has robust laws in place for regulating the practice of medicine.[275] Illinois already limits abortion care to licensed health care professionals who can provide such care based on accepted standards of clinical practice consistent with the scope of their practice, and in accordance with their professional judgment and training.[276] Accordingly, Illinois already has protections in place in relation to abortion care, including the prescribing of mifepristone, and the REMS provides no material patient protections beyond those afforded under existing professional standards.

Patient Agreement Form: Illinois already has informed consent laws that protect patients' rights and which would cover abortion care, including use of mifepristone.[277]

Pharmacy Certification*:* Illinois has long regulated the practice of pharmacy.[278] These provisions already include requirements for a pharmacist's scope of practice and proper labeling of drug containers to ensure patient safety.[279] Pharmacists are obligated to counsel patients on proper use of dispensed drugs.[280]

H. Maine

Prescriber Certification**:** Individuals in Maine with the relevant prescriptive authority, including allopathic and osteopathic physicians, physician assistants, and advanced practice registered nurses, must hold a valid state license from one of three state boards, or a valid compact privilege, to prescribe to Maine patients.[281] Failure to hold the required state license or privilege while prescribing to Maine patients subjects the unlicensed individual to civil or criminal liability.[282] To be licensed or privileged, all authorized prescribers must demonstrate requisite qualifications to the respective state board or interstate compact authority.[283] Once licensed or privileged, those with prescriptive authority are subject to discipline if they fail to

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[275] *See* Medical Practice Act of 1987, 225 Ill. Comp. Stat. 60/1 *et seq*., Physician Assistant Practice Act of 1987¸ 225 Ill. Comp. Stat. 95/1 *et seq.*, and Advanced Practice Registered Nurses, pursuant to the Nurse Practice Act, 225 Ill. Comp. Stat. 65/1 *et seq.* (which includes regulation of Advanced Practice Registered Nurses).

[276] 775 Ill. Comp. Stat. 55/1-25(a); *see also, e.g.*, 225 Ill. Comp. Stat. 60/22; Ill. Admin Code tit. 68, §§ 1330.30, 1285.240(d).

[277] *See* Medical Patient Rights Act, 410 Ill. Comp. Stat. 50/3(a).

[278] *See* Pharmacy Practice Act, 225 Ill. Comp. Stat. 85/1 *et seq.*

[279] *See, e.g*., 225 Ill. Comp. Stat. 85/22, 85/30; Ill. Admin Code tit. 68, §§ 1330.30, .500(d).

[280] *See* 225 Ill. Comp. Stat. 85/3(d)(8), 85/3(r); Ill. Admin Code tit. 68, § 1330.700.

[281] Me. Rev. Stat. tit. 22, § 1598(3); tit. 32, §§ 3270, 3270-E, 2571, 2594-E, 2106(3), 18504, 18506, and 18534 (2025).

[282] *Id.* tit. 10, § 8003-C; tit. 32, § 2106(3) (2025).

[283] *Id.* tit. 32, §§ 3271, 3270-E(2), 2571, 2594-E(2), 2102(2-A), 2201-A, 18504, 18506, and 18534; Me. Code R. §§ 02 373 1 §§ 2-4, and 6(10); 02 373 2, §§ 2-4; 02 383 2, §§ 2-4; and 02 380 8.

meet the standards of practice, standards of care, or codes of ethics for their practice area in treating any individual patient.[284] Any individual providing care via telehealth to a patient in Maine must also be licensed or privileged and must comport with the identical standards of care and professional conduct as an in-person provider.[285] The boards define incompetence to include (a) engaging in conduct that evidences a lack of ability or fitness to discharge the duty owed to a patient, or (b) engaging in conduct that evidences or a lack of knowledge or an inability to apply principles or skills to carry out the practice for which the licensee is licensed.[286] All licensees must be truthful and accurate in rendering the health care services they are licensed to provide.[287]

***Patient Agreement Form*:** All Maine licensees with the relevant prescriptive authority have the ethical and legal obligation to obtain informed consent from any patient pursuant to their standards of care, professional practice, and respective codes of ethics and would be subject to discipline if they failed to do so.[288]

***Pharmacy Certification*:** Pursuant to the Maine Pharmacy Act, Maine regulates and controls prescription drugs and the practice of pharmacy in Maine by regulating all pharmacists, pharmacy technicians all pharmacies that provide prescription drugs to Maine patients, as well as all wholesalers and distributors who sell prescription drugs to pharmacies, hospitals or practitioners.[289] Before dispensing a prescription drug to a patient, pharmacists are required to perform a drug utilization review to ensure patient safety, and to review all aspects of the prescription drug order, vial, and label for every prescription to ensure a given order is accurate in all respects.[290] A pharmacist may exercise their independent judgment and in their discretion refuse to fill any prescription.[291] For every new prescription dispensed, the pharmacist must ensure accurate labeling and must provide an oral explanation to the patient or the patient's agent of the directions for use, and all additional information necessary to assure the proper utilization of the prescribed drug.[292]

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[284] Me. Rev. Stat. tit. 32, §§ 3282-A(2)(E)-(F), 2591-A(2)(E)-(F), 2102(2-A)(C), 2105-A(2)(E)-(F), 18511, and 18536; Me. Code R. § 02 380 14.

[285] Me. Rev. Stat. tit. 32, §§ 3270, 3270-E, 2600-BB, 2600-DD, 2267, 2269, 18511, and 18536; Me. Code R. §§ 02 373 11, 02 383 11, and 02 380 11 (Joint Rule of the Boards of Licensure in Medicine, Osteopathic Licensure, and Nursing governing Telehealth Standards of Practice).

[286] Me. Rev. Stat. tit. 32, §§ 3282-A(2)(E)(1)-(2), 2591-A(2)(E)(1)-(2), and 2105-A(2)(E)(1)-(2).

[287] *Id*. §§ 3282-A(2)(A), 2591-A(2)(A), and 2105-A(2)(A).

[288] *Id*. §§ 3282-A(2)(E)-(F), 2591-A(2)(E)-(F), and 2105-A(2)(E)-(F); Me. Code R. § 02 380 14.

[289] Me. Rev. Stat. tit. 32, §§ 13721(1), 13731(2), and 13751.

[290] *Id*. §§ 13702-A(28), 13742-A(1)(C); Me. Code R. § 02 392 19, § 6(5).

[291] Me. Rev. Stat. tit. 32, §§ 13702(28), 13742-A(1)(C), and 13795(2).

[292] *Id.* § 13784(1).

I. Maryland

Prescriber Certification: The Maryland Board of Physicians regulates physicians' qualifications for licensure,[293] enforces detailed statutes as to what constitutes unprofessional conduct in the practice of medicine, professional incompetence, and/or failing to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care,[294] including a pattern of inappropriate prescribing,[295] and sets forth a detailed process by which such misconduct is determined.[296] Requirements for licensure, practice, and disciplinary processes for other qualified providers are similarly regulated under Maryland law.

Patient Agreement Form: Maryland patients have a common law right to informed consent of any material risks, benefits, and alternatives of the treatment so that the patient can make an intelligent and informed decision about the proposed treatment.[297]

Pharmacy Certification: The Maryland Board of Pharmacy regulates the practice of pharmacy, the licensure of pharmacists and the permitting, control and regulation of all pharmacy practice sites in the state.[298] Maryland pharmacists must exercise independent professional judgment as to whether to dispense or refill a prescription.[299] Pharmacists may refuse to dispense or refill a prescription based on professional judgment, experience, knowledge, or available reference materials, demonstrating the deliberate analysis of patient safety already required without the Pharmacy Agreement Form.[300] Maryland also has other specific requirements for dispensing and filling prescriptions,[301] including requirements for certain drugs to be clearly marked or labeled.[302]

J. Michigan

***Prescriber Certification*:** Michigan's Public Health Code is an extensive legislative framework that governs the licensing, regulation, monitoring, and supervision of medical providers, and through its legislative framework ensures that medical providers provide medical services within the standard of care for the profession.[303] Michigan has established a health

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[293] Md. Code Ann., Health Occ. §§ 14-201 and 205.
[294] *Id.* § 14-404(a).
[295] *Id.* § 14-404(a)(27).
[296] *Id.* §§ 14-401 through 408 and Code Md. Regulations, Title 10 § 32.02.
[297] *Sard v. Hardy*, 379 A.2d 1014 (1977).
[298] Md. Code Ann., Health Occ. § 12-101 through 12-802.
[299] *Id.* §§ 12-101(x)(v) and (vi).
[300] *Id.* § 12-501.
[301] *Id.* §§ 12-502, *et. seq*.
[302] *Id.* § 12-505.
[303] Mich. Comp. Laws § 333.1101 *et seq*.

oversight agency (the Department of Licensing & Regulatory Affairs, Bureau of Professional Licensing) charged with investigating and pursuing disciplinary actions against Michigan licensed medical providers for failing to practice within the standard of care.[304] The various health boards, like the Michigan Boards of Medicine and Osteopathic Medicine & Surgery, have created Disciplinary Subcommittees that impose sanctions against licensed health providers for failing to conform to the minimal standards of practice for the profession.[305] Licensed medical providers in Michigan are held to standard of care defined as a "violation of general duty, consisting of negligence or failure to exercise due care, including negligent delegation to or supervision of employees or other individuals, whether or not injury results, or any conduct, practice, or condition that impairs, or may impair, the ability to safely and skillfully engage in the practice of the health profession," or "a departure from, or failure to conform to, minimal standards of acceptable and prevailing practice for a health profession, whether or not actual injury to an individual occurs."[306] In making this determination, the Department retains medical experts who advise the boards on the standard of care in the medical community. These experts evaluate the care provided by licensed physicians based upon accepted medical literature and peer-reviewed research to determine whether the care provided is safe and effective medical practice. These practices bolster patient safety, eliminating the need for the Provider Agreement Form.

***Patient Agreement Form*:** The Patient Agreement Form is also unnecessary as the minimally acceptable standard of practice in Michigan requires all medical providers to obtain informed consent from any patient for any medical service or treatment being provided, regardless of whether the service involves reproductive care or other medical service. Presently MCL 333.17015 requires an additional informed consent specifically tailored for abortions that includes among other things a 24-hour waiting period and providing a patient with a medically accurate depiction, illustration, or photograph of the probable gestational age of the fetus.[307] However, on May 13, 2025, the Michigan Court of Claims found that many provisions of the statute's informed consent requirement violated the Michigan Constitution and constitute a denial, burden and/or infringement on reproductive freedom.[308] The Court of Claims left intact the requirement that a provider ensure a patient was not being coerced into obtaining an abortion and that the provider still owed a duty to inform patients of information pertaining to the procedure that a reasonably well-qualified physician would possess.[309] The Court of Claims opinion is currently on appeal with the Michigan Court of Appeals.

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[304] *Id.* §§ 333.16101-16299.

[305] *Id.* § 333.17001-17097; Mich. Admin. Code r. 338.2401-2443; Mich. Comp. Laws §§ 333.17501-17556; Mich. Admin. Code r. §§ 338.111-143.

[306] Mich. Comp. Laws §§ 333.16106(1), .16221(a) and (b)(i).

[307] *Id.* § 333.17015.

[308] *Northland Family Ctr. v Nessel*, No. 24-000011-MM (Mich. Ct. Cl.).

[309] *Id*.

***Pharmacy Certification*:** The Pharmacy Agreement Form is also redundant in Michigan as the Public Health Code already regulates licensing, dispensing, storing, and prescribing of prescription medication.[310] In Michigan, pharmacists have a duty to ensure the administration and dispensing of prescription medication is safe and effective, which involves counseling patients on the safe use and risks associated with taking a particular prescription medication, review of appropriate drug product selection, interpretation, and evaluation of the efficacy of the prescription, and ensuring the safe storage, dispensing, and labeling of the medication.[311] The Michigan Board of Pharmacy Disciplinary Subcommittee imposes sanctions against pharmacists for violating a general duty, and incompetence.

K. Minnesota

Prescriber Certification: Under Minnesota law, only licensed practitioners in the course of professional practice may prescribe legend drugs, including mifepristone.[312] An individual who prescribes mifepristone, or any drug or medicine without a license, may face criminal and civil penalties.[313] Minnesota has established a robust system of laws and regulations to protect the public from improper, unsafe, or unlawful practice of medicine.[314] These laws ensure that only qualified practitioners may be licensed to practice medicine.[315] Minnesota law also requires that licensed practitioners maintain ongoing continuing education as a condition of licensure so that a practitioner's medical knowledge and understanding of advances in the field remain up-to-date.[316] Further, unethical conduct in the practice of medicine or conduct that fails to conform to minimum standards of acceptable and prevailing medical practice is prohibited, as is any inappropriate or improper prescribing of drugs.[317] These existing protections render additional or special certification for the prescription of mifepristone unnecessary.

Patient Agreement Form: Licensed healthcare facilities in Minnesota are required by law to protect enumerated patient rights.[318] The law requires that providers give their patients "complete and current information concerning their diagnosis, treatment, alternatives, risks, and prognosis," and that patients have the right to refuse treatment or medication based on that information.[319] Further, Minnesota law establishes that individuals have the right to make autonomous decisions about the use of reproductive health care and whether to continue a

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[310] Mich. Comp. Laws §§ 333.17701-17780; Mich. Admin. Code r. 338.471-591, r. 3601-3642; r. 338.3651-3665.
[311] Mich. Comp. Laws § 333.17707(8).
[312] Minn. Stat. § 151.37, subd. 2(a).
[313] *Id.* §§ 147.081, subd. 2; 148.281; 214.11.
[314] *See id.* §§ 147.001, *et seq.*; 148.171-.285.
[315] *See id.* §§ 147.02-.0375; 148.211-.231.
[316] *See* Minn. R. 5605; Minn. Stat. § 148.231.
[317] Minn. Stat. §§ 147.091, subd. 1(g), (k), (s); 148.261, subd. 1(6), (7), (11).
[318] *See* Minn. Stat. § 144.651.
[319] *Id.*, subds. 9, 12.

pregnancy.[320] Minnesota's health-related licensing boards have strong systems for ensuring compliance with such requirements through their disciplinary processes, under which violation of laws ensuring informed consent and patient autonomy is grounds for discipline.[321]

Pharmacy Certification: The Minnesota Board of Pharmacy is duty-bound and empowered to regulate the practice of pharmacy and the retail sale of drugs, to examine and license pharmacists, to enter and inspect any places where drugs are sold or dispensed, and to access and inspect records related to the provision of drugs in the state.[322] Further, the Board of Pharmacy has promulgated an extensive system of rules regulating licensed pharmacists and pharmacies.[323] Those rules provide standardized, uniform processes for dispensing, verifying, and certifying prescriptions.[324] For example, all Minnesota pharmacies must maintain written patient consultation procedures with detailed requirements for pharmacists to consult with patients when dispensing a new prescription, including the name, description, dosage, intended use, and expected action of the drug; and common side effects and adverse effects and interactions.[325] In addition, the Board of Pharmacy is empowered to take disciplinary action against individuals and facilities for violating any of the statutes or rules of the Board.[326] Finally, dispensing mifepristone, or any other legend drug, without a valid prescription is illegal and may be prosecuted as a criminal offense.[327] Requiring special certification to dispense mifepristone is duplicative of these existing protections.

L. Nevada

Prescriber Certification: Nevada has robust laws in place for regulating the practice of medicine.[328] In Nevada, abortions must be performed by a physician[329] licensed to practice in the state or by a physician in the employ of the government of the United States.[330] In performing an abortion, the physician must exercise their best clinical judgment in the light of all attendant circumstances including the accepted professional standards of medical practice in determining whether to perform an abortion, and must perform the abortion in a manner consistent with accepted medical practices and procedures in the community.[331] The Nevada State Board of Medical Examiners is the state governmental agency which licenses and disciplines

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[320] *Id.* § 145.409, subd. 3.
[321] *See., e.g.*, *id.* §§ 147.091, subd. 1(f); 147A.13, subd. 1(6); 148.261, subd. 1(18).
[322] *Id.* § 151.06, subd. 1(a).
[323] *See generally*, Minn. R. 6800.0100, *et seq.*
[324] *See* Minn. R. 6800.3100.
[325] Minn. R. 6800.0910.
[326] Minn. Stat. § 151.071.
[327] *See* Minn. Stat. §§ 151.29; 151.34 (11).
[328] Nev. Rev. Stat. Ann. §§ 630.020-630.417.
[329] Nev. Rev. Stat. Ann. § 630.014 ("Physician" defined).
[330] *See* Nev. Rev. Stat. Ann. § 442.250.
[331] *Id*.

physicians.[332] The Nevada State Board of Medical Examiners may discipline a doctor if they provide services that they are not adequately trained to provide, or they do not maintain the skills needed to practice safely and effectively.[333] These laws ensure patient safety in the provision of medication abortion.

Patient Agreement Form: Nevada has comprehensive informed consent laws concerning abortions that protect patients' rights and which cover abortion care, including use of mifepristone.[334] Specifically, "[n]o physician may perform an abortion in [Nevada] unless, before the physician performs it, he or she obtains the informed consent of the woman seeking the abortion."[335] In Nevada, to obtain informed consent for abortion care, the physician must, among other things, inform the patient of the estimated gestational age; explain "[t]he procedure to be used and the proper procedures for her care after the abortion"; explain "[t]he discomforts and risks that may accompany or follow the procedure"; and "[o]ffer to answer any questions the woman has concerning the procedure."[336] In addition, the physician must provide the patient with a form indicating the patient's informed consent and must clearly describe the nature and consequences of the procedure to be used.[337] These robust protections for informed consent, render the Patient Certification form wholly unnecessary.

Pharmacy Certification: Nevada also regulates the practice of pharmacy[338] including requirements for placing the symptoms or purpose of the prescription on the label.[339] A pharmacist must also communicate matters which will enhance therapy through drugs with the patient.[340] The communication must include appropriate elements of counseling for the patient, as established in regulations adopted by the Nevada State Board of Pharmacy.[341] The Nevada State Board of Pharmacy's sole mission is to protect the health, safety, and welfare of Nevada's patients who use prescription drugs. The Board does this by licensing and regulating pharmacies and pharmacists,[342] and by investigating and initiating administrative proceedings against

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[332] Nev. Rev. Stat. Ann. § 630.130 (Enforcement of chapter: establishment of standards for licensure; administration of examinations; investigation of applicants and issuance of licenses; institution of court proceedings; submission of biennial report; regulations).

[333] Nev. Rev. Stat. Ann. § 630.306.

[334] Nev. Rev. Stat. Ann. § 442.252 (Physician to obtain informed consent before performing abortion) and § 442.253 (Requirements for informed consent).

[335] Nev. Rev. Stat. Ann. § 442.252.

[336] Nev. Rev. Stat. Ann. § 442.253.

[337] *Id.*

[338] Nev. Rev. Stat. Ann. § 639.070 (General powers; regulations).

[339] Nev. Rev. Stat. Ann. § 639.2352 (Inclusion of information regarding symptoms or purpose of prescription on label attached to container; practitioners required to post notice).

[340] Nev. Rev. Stat. Ann. § 639.266 (Communication of information to patient or person caring for patient).

[341] *Id.*

[342] Nev. Rev. Stat. Ann. § 639.070 (General powers; regulations).

pharmacies or pharmacists that have failed to serve the public well and safely.[343] At the request of the Board, the district attorney of the county wherein the statutory violations occurred shall conduct a civil action or criminal prosecution.[344] The Board also conducts inspections of pharmacies to ensure compliance with state and federal laws and regulations.[345] These strict safeguards render imposition of the Pharmacy Certification ETASU unnecessary.

M. New Mexico

Prescriber Certification: The Prescriber Certification is unduly burdensome as it is duplicative of protections already enshrined in New Mexico law. The New Mexico Medical Practice Act's primary purposes are "public health, safety and welfare and to protect the public from the improper, unprofessional, incompetent and unlawful practice of medicine."[346] This Act established the New Mexico Medical Board which is tasked with controlling the "privilege to practice medicine" in the state.[347] The Board disciplines practitioners and regulates licensure for "the practice of medicine" which includes dispensing and prescribing medication.[348] These statutory licensure requirements ensure only qualified practitioners of "good moral character" practice medicine in New Mexico,[349] thus already accomplishing what is purportedly achieved by the Prescriber Certification.

Patient Agreement Form: Similarly, the existing patient protections and informed consent requirements in New Mexico render the Patient Agreement Form unnecessary. Regulations on the practice of medicine in New Mexico center informed consent as fundamental to an "established physician-patient relationship" and medical ethics.[350] Those practicing medicine in New Mexico are prohibited from prescribing medications to patients without a physician-patient relationship predicated on informed consent.[351] Violations of this prohibition are considered unprofessional and dishonorable conduct which is regulated and punished by the New Mexico Medical Board.[352] The robust reliance on informed consent in New Mexico negates any need for the unduly burdensome Patient Agreement Form.

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[343] Nev. Rev. Stat. Ann. § 639.210 (Grounds for suspension or revocation of certificate, license, registration or permit or denial of application) and § 639.241 et seq. (Administrative Proceedings).

[344] Nev. Rev. Stat. Ann. § 639.300 (Recovery of penalties; conduct of actions and prosecutions by district attorney).

[345] Nev. Admin. Code § 639.501; *id.* § 639.5016; Nev. Rev. Stat. Ann. § 639.090 (Enforcement of chapter; inspections).

[346] N.M. Stat. Ann. § 61-6-1 (2021).

[347] *Id*.

[348] N.M. Stat. Ann. § 61-6-6(J) (2023).

[349] N.M. Stat. Ann. § 61-6-11 (2021).

[350] N.M. Admin. Code §16.10.8.7; *see also* N.M. Admin. Code § 16.10.16.7(D).

[351] N.M. Admin. Code §16.10.8.8(L).

[352] N.M. Stat. Ann. § 61-6-15(A) (2023).

Pharmacy Certification: The Pharmacy Certification imposes an unnecessary burden on New Mexico pharmacies, as state law already contains strict requirements on pharmacies to ensure competency and patient safety.[353] The New Mexico Board of Pharmacy regulates not only licensure, but the activities and duties of pharmacists in the provision of care, medication regimen review, and patient counseling.[354] Pharmacists in New Mexico are required to maintain records of drugs deemed "dangerous" that are open to inspection by the Board of Pharmacy.[355] The Board also enforces state laws pertaining to the sale and distribution of medications such as the New Mexico Drug, Device and Cosmetic Act.[356] All persons licensed as pharmacists in New Mexico are listed on a registry maintained by the Board.[357] Regulations require pharmacists to provide professional consultation to patients and with prescribers, as well as review drug regimens utilizing their professional judgment.[358] The requirement of the Pharmacy Certification only imposes additional burdens on healthcare delivery without added benefit to patients.

N. Oregon

Prescriber Certification: With limited exceptions, Oregon law prohibits the practice of medicine without a state-issued medical license.[359] The Oregon Medical Board sets the exacting qualifications and standards required of medical license applicants; exercises general supervision over the practice of medicine; and enforces the Oregon Medical Practice Act's requirements.[360] Practicing medicine without a license or other specific, statutorily defined authorization is a Class C felony.[361]

A licensed physician in Oregon has the duty to use the degree of care, skill and diligence that is used by ordinarily careful physicians in the same or similar circumstances.[362] The Oregon Medical Board may suspend or revoke a physician's license to practice medicine for engaging in conduct or practices that fail to comply with recognized ethics standards, that endangers the health or safety of a patient, or that might adversely affect the physician's ability to safely and skillfully practice medicine.[363]

The Prescriber Certification Form imposes a redundant and unnecessary administrative burden on Oregon's health practitioners. Oregon law already requires physicians to apply their

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[353] N.M. Stat. Ann. §§ 61-11-1 -31 (1969, as amended through 2025).
[354] N.M. Stat. Ann. § 61-11-6(A)(18) (2022).
[355] N.M. Stat. Ann. § 61-11-8 (1997).
[356] N.M. Stat. Ann. §§ 26-1-1 to -27 (1987, as amended through 2025).
[357] N.M. Admin. Code §16.19.1.11.
[358] N.M. Admin. Code §16.19.4.16(A).
[359] Or. Rev. Stat. § 677.080.
[360] *Id.* § 677.265.
[361] *Id.* §§ 677.080, 677.990(2).
[362] *Id.* § 677.095(1).
[363] *Id.* §§ 677.190(1)(a), 677.188(4).

knowledge, experience, and expertise while exercising due care, including when prescribing medications such as mifepristone.[364]

Patient Agreement Form: Oregon law already requires informed consent for medical procedures and treatment, including when prescribing medications such as mifepristone.[365]

Pharmacy Certification: Like medicine, the practice of pharmacy is closely regulated in Oregon.[366] Under the Oregon Pharmacy Act, a person must be licensed to practice pharmacy.[367] The State Board of Pharmacy sets licensing qualifications and standards for applicants while enforcing requirements governing the conduct and competence of licensed pharmacists.[368] The unlawful practice of pharmacy is a Class A misdemeanor.[369]

A practicing pharmacist must use the degree of care, skill, diligence, and reasonable professional judgment that would be exercised by a careful and prudent pharmacist in the same or similar circumstances.[370] A pharmacist may not disclose confidential patient information or act contrary to accepted standards of practice.[371] A pharmacist must also maintain records regarding the acquisition, storage, dispensing or administration, and disposal of drugs, including mifepristone.[372] In light of these requirements, the Pharmacy Certification Form is redundant and unnecessary.

O. Pennsylvania

Prescriber Certification: In the Commonwealth of Pennsylvania, a prescriber of mifepristone is required to comply with a multitude of statutes and regulations. First, an abortion "shall be performed only by a physician who possesses the requisite professional skill and competence as determined and approved by the medical facility in accordance with appropriate procedures."[373] Second, physicians are required to adhere to the standard of care in all instances of patient care, including the prescribing of medication and performance of any procedure or treatment.[374] Third, a prescriber dispensing any drug is required to label the drug in a manner that includes the directions for use of the drug by the patient.[375] A prescriber who fails to follow the applicable statutes and regulations may be subject to criminal, civil, and licensing

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[364] *See id.* § 677.085(4).
[365] *Id.* § 677.097; *see also* https://www.oregon.gov/omb/topics-of-interest/pages/informed-consent.aspx.
[366] Or. Rev. Stat. § 689.025.
[367] *Id.* § 689.225(1).
[368] *Id.* § 689.151.
[369] *Id.* § 689.995(1).
[370] Or. Admin. R. § 855-115-0105(1).
[371] *Id.* § 855-006-0020(g), (j).
[372] *Id.* § 855-115-0125(8)(c).
[373] 28 Pa. Code § 29.33(3).
[374] 63 Pa. Cons. Stat. § 422.41(8); 63 P.S. § 271.15(8).
[375] 49 Pa. Code § 16.94(a).

penalties.[376, 377, 378] Given the existing requirements under Pennsylvania laws and regulations, and the consequent penalties for violations of applicable statutes and regulations, the Prescriber Certification is duplicative and unduly burdensome.

Patient Agreement Form: The Patient Agreement form replicates, in pertinent part, the existing informed consent requirements set forth in the Abortion Control Act ("ACA") and the general surgical consent required in the Commonwealth. Specifically, both the FDA and the ACA require the informed consent of the patient, with such consent attested to by the patient in writing. In the Commonwealth of Pennsylvania, the physician is required to consult with the patient at least 24 hours prior to the abortion, with the consent likewise required to be obtained by the provider at least 24 hours prior. [379] The consent is considered to be informed only when the following information is provided: nature of proposed procedure or treatment and the attendant risks and alternatives to the procedure or treatment; probable gestational age; and medical risks associated with carrying the child to term.[380] In addition, the patient is required to be informed of the available agencies who may assist with abortion alternatives, a description of the unborn child, the liability of the father as it relates to support of the child, and information relating to medical assistance benefits for prenatal care, childbirth and neonatal care.[381] Further, this information must be made available to the patient in printed form when she so chooses to receive it in that medium.[382] In addition to the foregoing, informed consent is required to be obtained from all patients prior to the performance of surgery.[383] The informed consent statutory structure in the Commonwealth is robust; as such, it is inclusive of the elements of the FDA Patient Agreement form necessary for patient information and safety. Thus, the Patient Agreement form is unduly burdensome given its redundancy.

Pharmacy Certification: The Pennsylvania State Board of Pharmacy regulates pharmacist licensing[384], professional conduct, standards of practice[385], delegation of duties[386], and provides guidelines on how pharmacies are to be operated.[387] Pharmacists licensed in the Commonwealth are required to conduct a Prospective Drug Review (PDR) before filling, delivering, or sending a new prescription or drug order.[388] Additionally, pharmacists are required to offer patient counseling when the pharmacist fills, delivers or sends a new retail or outpatient

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[376] 18 Pa. Cons. Stat. §§ 3204(d), 3205(c), 3206(i), 3210(b), 3211(d), 3214(i), 3218, and 3219.
[377] 18 Pa. Cons. Stat. § 3219.
[378] 63 Pa. Cons. Stat. § 422.41(8); 63 Pa. Cons. Stat. § 271.15(a)(8)
[379] 18 Pa. Cons. Stat. § 3205(a); 28 Pa. Code § 29.37.
[380] *Id.*
[381] *Id.*
[382] *Id.*
[383] 40 Pa. Cons. Stat. § 1303.504(a).
[384] 63 Pa. Cons. Stat. §§ 390-1—390-13.
[385] 49 Pa. Code § 27.18.
[386] 49 Pa. Code § 27.12.
[387] 49 Pa. Code §§ 27.13—27.17.
[388] 49 Pa. Code § 27.19(a).

prescription.[389] The development and implementation of a system to confidentially track prescriber certifications and filled prescriptions is a significant burden on Pennsylvania pharmacies who are currently required to follow a dearth of statutes and regulations encompassing patient safety. Accordingly, Pennsylvania pharmacists currently ensure patient safety through adherence to these requirements without the need for a Pharmacy Agreement Form.

P. Rhode Island

Prescriber Certification: Rhode Island has enacted comprehensive laws and regulations which effectively govern the practice of medicine and ensure adherence to prevailing standards by all who practice medicine in the state of Rhode Island. Its regulations establish the qualifications of prescribers and responsibilities of healthcare providers.[390] Further, the Rhode Island Board of Medical Licensure and Discipline oversees the implementation of these laws and ensures compliance with the standards they require, including issuing discipline for unprofessional conduct.[391] "Incompetent, negligent, or willful misconduct in the practice of medicine, which includes the rendering of medically unnecessary services, and any departure from, or the failure to conform to, the minimal standards of acceptable and prevailing medical practice in his or her area of expertise as is determined by the board" is considered "unprofessional conduct," according to RIGL § 5-37-5.1, as is "violating any state or federal law or regulation relating to controlled substances," and "failing to maintain standards established by peer-review boards, including, but not limited to: standards related to proper utilization of services, use of nonaccepted procedure, and/or quality of care."[392] Rhode Island's laws and regulations governing licensing of medical professionals and professional conduct require and ensure that only qualified providers are able to prescribe mifepristone, and only for appropriate indications. The Prescriber Certification requirement of the REMS is unnecessary, duplicative, and irrelevant.

Patient Agreement Form: The Patient Agreement Form is likewise unnecessary and redundant on top of the already incredibly onerous informed consent requirements already imposed by Rhode Island state law. Rhode Island law requires specific written consent for abortion on a form which includes specific disclosures regarding the estimated gestational age, the medical or surgical nature of the abortion, all known material risks, and specific language regarding options.[393] Rhode Island law also contains requirements for parental consent in the case of minors requiring abortion, and it ensures that the written informed consent form is provided in a language the patient understands or certified by an interpreter.[394] The Patient

[389] 49 Pa. Code § 27.19(d)(1).
[390] 216 R.I. Code R.40-05-1.
[391] R.I. Gen. L. § 5-37-1.3.
[392] R.I. Gen. L. § 5-37-5.1.
[393] R.I. Gen. L. § 23-4.7-1 *et seq*.
[394] R.I. Gen. L. § 23-4.7-6.

Agreement Form adds nothing by way of protection for the patient but adds significant administrative burden to the provider and healthcare system.

Pharmacy Certification: The regulation of pharmacy practice in Rhode Island is governed by comprehensive laws and regulations. The Pharmacy Agreement Form is redundant to and in excess of these provisions. Rhode Island prohibits the unlicensed practice of pharmacy[395] and requires that all Pharmacies and Pharmacists adhere to a code of professional conduct.[396] Rhode Island requires that Pharmacists initiate discussion of matters that will enhance or optimize drug therapy with each patient or patient's care giver.[397] The Rhode Island Board of Pharmacy regulates the practice of pharmacy and enforces all laws relating to pharmacy.[398] Requiring special certification to dispense mifepristone is superfluous to the existing requirements and responsibilities already imposed by law on Rhode Island pharmacies and pharmacists.

Q. Vermont

Prescriber Certification: In Vermont, a healthcare professional's scope of practice is based on their education, training, and experience. Physicians are licensed, regulated, monitored, certified and accredited through the Vermont Department of Health's Board of Medical Practice,[399] and Vermont's doctors of osteopathy are licensed and regulated through Vermont's Board of Osteopathic Physicians and Surgeons.[400] The Vermont Board of Medical Practice protects and promotes the public health, safety, and welfare by ensuring professional integrity through licensure and investigation of complaints. Physicians practicing medicine outside the defined scope of practice can lead to disciplinary action by the Vermont Board of Medical Practice including penalties, license restrictions, suspension, or revocation.[401]

Patient Agreement Form: In Vermont, health care providers are required to obtain a patient's informed consent prior to treatment.[402] This includes providing a patient with treatment options and alternatives as well as discussing foreseeable risks and benefits "in a manner permitting the patient to make a knowledgeable evaluation."[403] A patient in Vermont is entitled to "a reasonable answer to any specific question about foreseeable risks and benefits, and a medical practitioner shall not withhold any requested information."[404]

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[395] R.I. Gen. L. § 5-19.1-9.
[396] 216 R.I. Code R.40-15-1.
[397] 216 R.I. Code R.40-15-1.5.14.
[398] R.I. Gen. L. § 5-19.1-5.
[399] 26 Vt. Stat. Ann. § 1311 *et seq*.
[400] 26 Vt. Stat. Ann. § 1750 *et seq*.
[401] 26 Vt. Stat. Ann. § 1354.
[402] 12 Vt. Stat. Ann. § 1909.
[403] 12 Vt. Stat. Ann. § 1909(a).
[404] 12 Vt. Stat. Ann. § 1909(d).

Pharmacy Certification: Vermont's pharmacies are regulated by its Board of Pharmacy.[405] The dispensing of prescription medications in Vermont is governed by statute.[406] Vermont's laws and Board of Pharmacy Rules protect patients with strict requirements and guidance regarding the receiving of prescription medication and distribution of prescription drugs.[407] Pharmacists must follow specific requirements for licensure (exam and license) and must engage in continuing pharmacy education.[408]. Pharmacists must also follow specific standards for pharmacies where they work and must engage in detailed pharmacy practice, as outlined in the Rules, and may be disciplined for failure to do so.[409]

R. Washington

Prescriber Certification: In general, no person may practice medicine in Washington state without a license.[410] In Washington, a physician, physician assistant, advanced registered nurse practitioner, or other health care provider acting within the provider's scope of practice may provide a medication abortion.[411] These health care providers are subject to regulation of their practice by their respective disciplining authorities under the Uniform Disciplinary Act.[412] Disciplining authorities have authority to investigate and initiate enforcement action against licensed health providers for failing to meet the applicable standard of care, practicing beyond the provider's scope of practice, prescribing drugs in any way other than for legitimate or therapeutic purposes, or engaging in other unprofessional conduct, as defined at RCW 18.130.180.[413] Disciplining authorities can suspend or revoke licenses, limit practice, levy fines, and impose other sanctions on licensees.[414] These protections obviate the need for a Prescriber Certification for mifepristone.

Patient Agreement Form: Washington law imposes a duty on health care providers to obtain informed consent from patients.[415] Specifically, a provider has a duty to inform a patient of all material facts, including risks and alternatives, that a reasonably prudent patient would need in order to make an informed decision on whether to consent to or reject a proposed course of treatment.[416] Thus, in the context of medication abortion, an abortion provider in Washington must ensure that the patient has all material facts related to the treatment, including the risks and

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[405] 26 Vt. Stat. Ann. § 2031.
[406] 18 Vt. Stat. Ann. § 4201 *et seq*.; 26 V.S.A. § 2021 *et seq*.
[407] 18 Vt. Stat. Ann. Chapter 84.
[408] 26 Vt. Stat. Ann. § 2042.
[409] *Id.*
[410] Wash. Rev. Code § 18.71.011, .021, .030(4); *see also State v. Wilson*, 528 P.2d 279 (1974).
[411] Wash. Rev. Code § 9.02.110.
[412] Wash. Rev. Code § 18.130 *et seq*.
[413] Wash. Rev. Code §§ 18.130.050, .080, .090.
[414] Wash. Rev. Code § 18.130.160.
[415] *See* Wash. Rev. Code § 7.70.050; *Backlund v. Univ. of Wash.*, 975 P.2d 950, 955 (1999).
[416] Wash. Rev. Code § 7.70.050.

alternatives, in order to obtain a patient's informed consent. In addition, providers face discipline for "engaging in incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed," or undertaking "misrepresentation or fraud in any aspect of the conduct of the business or profession."[417] The Patient Agreement Form is unnecessary in light of these requirements to obtain informed consent.

Pharmacy Certification: The Washington State Pharmacy Quality Assurance Commission oversees the practice of pharmacy in Washington. Its primary role is to protect the public by ensuring the safe and effective delivery of pharmaceutical care. This includes licensing pharmacists, pharmacies, and other related personnel and firms, setting standards of practice, and investigating complaints or violations. Washington sets strict requirements for pharmacy facilities.[418] When a practitioner dispenses abortion medication in Washington, Washington law requires them to apply a label bearing the name of the prescriber (or prescribing and dispensing health care facility if preferred), complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date.[419] Failure to comply with these requirements is a misdemeanor.[420] Notably, under Washington law, in an effort to protect the confidentiality of abortion care providers, "the prescription label for abortion medications may include the prescribing and dispensing health care facility name instead of the name of the practitioner" if the prescriber requests such confidentiality.[421] Further, Washington law requires pharmacists to offer counseling to patients receiving new prescriptions or when they, in their professional judgment, deem it necessary for safe and effective medication use.[422] The Pharmacy Quality Assurance Commission has broad authority to take disciplinary action against pharmacies and pharmacy professionals for violating any of the foregoing requirements or any other applicable pharmacy law.[423] Imposing an additional certification to dispense mifepristone is unnecessary given these existing protections.

[417] Wash. Rev. Code §§ 18.130.180(4), (13).
[418] Wash. Admin. Code § 246-945-410.
[419] Wash. Rev. Code § 69.41.050.
[420] Wash. Rev. Code § 69.41.050(3).
[421] Wash. Rev. Code § 69.41.050(2)(a).
[422] Wash. Admin. Code § 246-945-325.
[423] Wash. Rev. Code §§ 18.64.026, 18.130.160.

* * *

In sum, given mifepristone's well-established safety record in the United States over the last 25 years, its critical importance for abortion care and miscarriage management in Petitioner States, and the undue burdens the Mifepristone REMS Program places on patient access and the healthcare delivery system, the Mifepristone REMS Program should be removed in its entirety, or alternatively, FDA should exercise its discretion not to enforce the Mifepristone REMS Program (or elements thereof) in Petitioner States.

ENVIRONMENTAL IMPACT

The proposed action is exempt from the requirement of an environmental impact statement under 21 C.F.R. § 25.30, 25.31, 25.32, 25.33, or § 25.34 or an environmental assessment under 21 C.F.R. § 25.40.

ECONOMIC IMPACT

Petitioner States will submit an economic impact statement should the Commissioner request such information following review of this petition.

CERTIFICATION

The Petitioner States certify that, to the best of our knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Respectfully,

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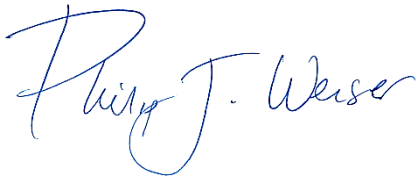

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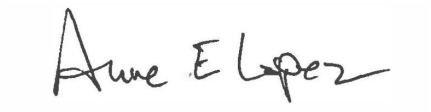

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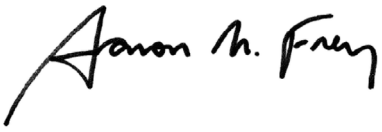

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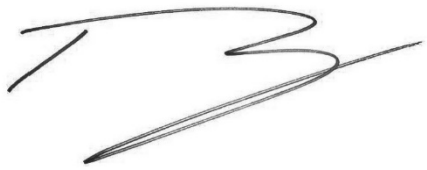

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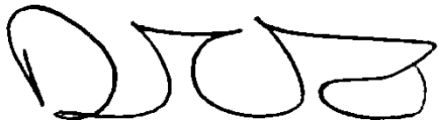

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