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CLERK OF THE SUPREME COURT
STATE OF MONTANA

Case Number: DA 22-0207

#### IN THE SUPREME COURT OF THE STATE OF MONTANA No. DA 22-0207

HELEN WEEMS AND JANE DOE,

Plaintiffs and Appellees,

v.

THE STATE OF MONTANA, by and through AUSTIN KNUDSEN, in his official capacity as ATTORNEY GENERAL, and TRAVIS R. AHNER, in his official capacity as the COUNTY ATTORNEY FOR FLATHEAD COUNTY,

Defendants and Appellants.

# BRIEF FOR THE NATIONAL ASSOCIATION OF NURSE PRACTITIONERS IN WOMEN'S HEALTH AND THE AMERICAN COLLEGE OF NURSE-MIDWIVES AS AMICI CURIAE

On Appeal from the Montana First Judicial District Court, Lewis and Clark County, the Honorable Mike Menahan, Presiding

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## TABLE OF AUTHORITIES

## Regulations

Mont. Admin. R. 24.159.1406(1)
Mont. Admin. R. 24.159.1406(1)(b)
Mont. Admin. R. 24.159.141211
Mont. Admin. R. 24.159.1461(1)
Mont. Admin. R. 24.159.1463
Mont. Code Ann. § 37-8-202(1)(h)
Mont. Code Ann. § 50-20-109(1)(a)
OTHER AUTHORITIES
ACOG Opinion No. 612, Am. C. of Obstetricians and Gynecologists (Nov. 2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Abortion-Training-and-Education
ACOG Statement on Medication Abortion (Mar. 2016)9
ACOG, Committee Opinion No. 815, Increasing Access to Abortion, 136(6) Obstet. & Gynecol. e107 (2020)
ACOG, Practice Bulletin No. 183, Postpartum Hemorrhage, 130(4) Obstet. & Gynecol. e168 (2017)
ACOG, Practice Bulletin No. 222, Gestational Hypertension and Preeclampsia, 135(6) Obstet. & Gynecol. e237 (2020)8
ACOG, Practice Bulletin No. 225, Medication Abortion Up to 70 Days of Gestation, 136(4) Obstet. & Gynecol. e31 (2020)9
Aimee C. Holland, Brandi Shah et al., <i>Preparing for Intrauterine Device Consults and Procedures</i> , Women's Healthcare (Dec. 2020), https://www.npwomenshealthcare.com/wp-content/uploads/2020/11/WHC1220_IUDConsultsProcedures.pdf

Amy J. Levi and Tara Cardinal, Early Pregnancy Loss Management for Nurse Practitioners and Midwives, Women's Healthcare: A Clinical Journal for NPs (2016), https://npwomenshealthcare.com/early-pregnancy-loss-management-nurse-practitioners-midwives/	.14
ANSIRH, U.S. Studies on Medication Abortion Without In-person Clinician Dispensing of Mifepristone (2021), at 1	9
Caron Kim, Annik Sorhaindo et al., WHO Guideline and the Role of the Physician in Task Sharing in Safe Abortion Care, Vol. 63, Best Practice & Research Clinical Obstetrics & Gynaecology at 59 (Feb. 2020)	.18
Courtney B. Jackson, <i>Expanding the Pool of Abortion Providers: Nurse-Midwives, Nurse Practitioners, and Physician Assistants</i> , Women's Health Issues 21-3S (2011) at S42, https://www.whijournal.com/action/showPdf?pii=S1049-3867%2811%2900011-9	.15
Definition of Midwifery and Scope of Practice of Certified Nurse-Midwives and Certified Midwives (Dec. 2021), Am. C. of Nurse Midwives, https://www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/000 000000266/Definition%20Midwifery%20Scope%20of%20Practice_2021. pdf	. 13
Elizabeth G. Raymond & David A. Grimes, <i>The Comparative Safety of Legal Induced Abortion and Childbirth in the United States</i> , 119 Obstetrics & Gynecology 215 (2012)	8
Eva Patil, Blair Darney et al., Aspiration Abortion with Immediate Intrauterine Device Insertion: Comparing Outcomes of Advanced Practice Clinicians and Physicians, 61 J. Midwifery & Women's Health 325 (2016)	. 18
Evensen et al., <i>Postpartum Hemorrhage: Prevention and Treatment</i> , 95(7) Am. Fam. Physician 442 (2017)	8
François Blondeau & Nach G. Daniel, <i>Extraction of Impacted Mandibular Third Molars: Postoperative Complications and Their Risk Factors</i> , 73 J. Can. Dental Assoc. 325 (2007)	6

Georgina Castro, M. Fuad Azrak et al., Outpatient Colonoscopy Complications in the CDC's Colorectal Cancer Screening Demonstration Program: A Prospective Analysis, 119 Cancer 2849 (2013)
H. Kopp Kallner, et al, <i>The Efficacy, Safety and Acceptability of Medical Termination of Pregnancy Provided by Standard Care by Doctors or by Nurse-midwives: A Randomised Controlled Equivalence Trial</i> , 122 BJOG: An Int'l J. of Obstetrics and Gynaecology 510 (2014)
Ina Warriner et al., Rates of Complication in First-trimester Manual Vacuum Aspiration Abortion Done by Doctors and Mid-level Providers in South Africa and Vietnam: A Randomised Controlled Equivalence Trial, 368  Lancet 1965 (2006)
Jack L. Paradise, Charles D. Bluestone et al., <i>Tonsillectomy and Adenotonsillectomy for Recurrent Throat Infection in Moderately Affected Children</i> , 110 Pediatrics 7 (2002)
Jatlaoui et al., <i>Abortion Surveillance—United States</i> , 2015, 67 Morbidity & Mortality Weekly Rep. 1 (2018)
Jose Granell, Pilar Gete et al., Safety of Outpatient Tonsillectomy in Children: A Review of 6 Years in a Tertiary Hospital Experience, 134 Otolaryngology – Head & Neck Surgery 383 (2004)
Justin J. Chu, Adam J. Devall et al., <i>Mifepristone and Misoprostol versus Misoprostol Alone for the Management of Missed Miscarriage (MifeMiso): a Randomised, Double-Blind, Placebo-Controlled Trial</i> , 396 Lancet 770 (Sept. 12, 2020), https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2931788-8
Letter from Janet Woodcock, M.D., Acting Commissioner of Food and Drugs, FDA, to Maureen G. Phipps, MD, MPH, FACOG, CEO, ACOG (Apr. 12, 2021)
Lydia Mainey, Catherine O'Mullan et al., <i>The Role of Nurses and Midwives in the Provision of Abortion Care: A Scoping Review</i> , J. of Clinical Nursing at 1 (Feb. 2020)

Midwives as Abortion Providers, Am. C. of Nurse-Midwives http://www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/0000 00000314/PS-Midwives-as-Abortion-Providers-FINAL-August-2019 22-2	23
Montana Board of Nursing Recognized National Professional Organizations (NPO) for APRN Scope and Standards of Practice, Mont. Dep't of Lab. & Industry (Aug. 2018), http://boards.bsd.dli.mt.gov/Portals/133/Documents/nur/aprn_sop_documents.pdf.	12
National Academies of Sciences, Engineering, Medicine, <i>The Safety and Quality of Abortion Care in the United States</i> (2018)	6
National Association of Nurse Practitioners in Women's Health, <i>Resolution on Nurse Practitioners as Abortion Providers</i> (October 1991), https://5aa1b2xfmfh2e2mk03kk8rsx-wpengine.netdna-ssl.com/wp-content/uploads/CNM_NP_PA_org_statements.pdf	22
National Women's Health Network, <i>Safe, Online, Delivered: How to Get the Abortion Pill by Mail</i> (Mar. 8, 2021), https://nwhn.org/safe-online-delivered-how-to-get-the-abortion-pill-by-mail	9
Position Paper on Principals of Abortion & Access to Comprehensive Reproductive Health Services, Am. Med. Women's Ass'n, https://www.amwa-doc.org/wp-content/uploads/2018/05/Abortion-and-Access-to-Comprehensive-Reproductive-Health-Services.pdf	21
Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants, Am. Pub. Health Ass'n (Nov. 1, 2011), https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/28/16/00/provision-of-abortion-care-by-advanced-practice-nurses-and-physician-assistants	20
Roosa Tikkanen et al., Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries, Commonwealth Fund (Nov. 18, 2020)	8
Scope of Practice for Nurse Practitioners, Am. Ass'n of Nurse Practitioners (2015), https://www.aanp.org/images/documents/publications/scopeofpractice.pdf. 12,	13

Shireen J. Jejeebhoy et al., Can Nurses Perform Manual Vacuum Aspiration (MVA) As Safely and Effectively As Physicians? Evidence From India, 84 Contraception 615 (2011)
Tracy A. Weitz, Diana Taylor et al., Safety of Aspiration Abortion  Performed by Nurse Practitioners, Certified Nurse Midwives, and  Physician Assistants Under a California Legal Waiver, 103 Am. J. Pub.  Health 454 (2013)
U.S. Department of Justice, Diversion Control Division, <i>Mid-Level Practitioners Authorization by State</i> , https://www.deadiversion.usdoj.gov/drugreg/practioners/ (last visited Sept. 18, 2022)
Ushma D. Upadhyay et al., <i>Incidence of Emergency Department Visits and Complications After Abortion</i> , 125 Obstetrics & Gynecology 175 (2015)6,7
Ushma D. Upadhyay, <i>Safety of Abortion in the United States</i> , Advancing New Standards In Reprod. Health (Dec. 2014), https://www.ansirh.org/sites/default/files/publications/files/safetybrief12-14.pdf
What's an NP?, Am. Ass'n of Nurse Practitioners, https://www.aanp.org/all-about-nps/what-is-an-np#services (last visited Nov. 14, 2018)
White et al., Complications from First-Trimester Aspiration Abortion: A  Systematic Review of the Literature, 92 Contraception 422 (2015)7
World Health Organization, <i>Abortion Care Guideline</i> (2022), at 59, https://www.who.int/publications/i/item/9789240039483
World Health Organization, Safe Abortion: Technical and Policy Guidance for Health Systems (2d ed. 2012)
Zane et al., <i>Abortion-Related Mortality in the United States</i> 1998-2010, 126  Obstet. & Gynecol. 258 (2015)5

#### I. INTEREST OF THE AMICI

Amicus curiae National Association of Nurse Practitioners in Women's Health ("NPWH") is the professional community for Women's Health Nurse Practitioners and other advanced practice registered nurses who provide women's and gender-related healthcare. NPWH sets a standard of excellence by translating and promoting the latest research and evidence-based clinical guidance, providing high quality continuing education, and advocating for patients, providers, and the women's health nurse practitioner profession. NPWH's mission includes protecting and promoting a woman's right to make her own choices regarding her health and well-being within the context of her lived experience and her personal, religious, cultural, and family beliefs.

Amicus curiae American College of Nurse-Midwives ("ACNM") is the professional association that represents certified nurse-midwives ("CNMs") and certified midwives ("CMs") in the United States. ACNM sets the standard for excellence in midwifery education and practice in the United States and strengthens the capacity of midwives in developing countries. Members of ACNM are primary care providers for women throughout the lifespan, with a special emphasis on pregnancy, childbirth, and gynecologic and reproductive health. ACNM's mission is to support midwives, advance the practice of midwifery, and achieve optimal, equitable health outcomes for the people and communities

midwives serve through inclusion, advocacy, education, leadership development and research.

NPWH and ACNM are interested in this matter because the resolution of the issue before the Court impacts the health and well-being of women in Montana as well as the ability of many of Montana's healthcare providers to provide necessary healthcare services to their patients. Specifically, enforcement of Montana Code Ann. § 50-20-109(1)(a), which limits the provision of abortions to physicians and physician assistants (the "APRN Restriction") affects Montanans' access to abortion care and infringes upon Montanans' fundamental right to choose the qualified abortion care provider of their choice. Safety concerns do not warrant restricting abortion providers to physicians and physician assistants. Abortion is an extremely safe form of health care that has been, and should continue to be, competently and effectively provided by Advanced Practice Registered Nurses.

#### II. SUMMARY OF ARGUMENT

The APRN Restriction prohibits Advanced Practice Registered Nurses

("APRNs")—professional nurses with advanced education and training, including certified nurse practitioners and certified nurse-midwives<sup>1</sup>—from providing

<sup>&</sup>lt;sup>1</sup> Certified nurse practitioners ("CNPs") and CNMs both have advanced clinical training beyond their initial professional registered nurse education. CNPs are trained to provide a full range of primary, acute and specialty health care services, including ordering, performing and interpreting diagnostic tests, diagnosing and treating acute and chronic conditions, prescribing medications, managing patients'

abortion services in Montana. Only physicians and physician assistants are permitted to provide abortions in the State.

In 2018, Plaintiffs-Appellees Weems and Doe (the "Clinicians") sought a preliminary injunction to prevent enforcement of the APRN Restriction, arguing that it imposed irreparable harm on Montanans by depriving them of their fundamental constitutional right to seek abortion services from a healthcare provider of their choice. The district court issued a preliminary injunction. This Court upheld the injunction following an appeal brought by the State of Montana and County Attorney Corrigan. Following discovery, the district court granted summary judgment in favor of the Clinicians. The State of Montana and now-County Attorney Ahner appealed.

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overall care, counseling, and educating patients on disease prevention and lifestyle choices. *See What's an NP?*, Am. Ass'n of Nurse Practitioners,

https://www.aanp.org/all-about-nps/what-is-an-np#services (last visited Sept. 17, 2022). CNMs independently provide a full range of health care services, including primary care, sexual and reproductive health, gynecologic and family planning services, preconception care, and care during pregnancy, childbirth and the postpartum periods. Midwives provide comprehensive assessment, diagnosis and treatment, which includes physical examination, prescriptive care, ordering and interpreting laboratory and diagnostic tests, and home health services. *See* Am. C. of Nurse Midwives, *Definition of Midwifery and Scope of Practice of Certified Nurse-Midwives and Certified Midwives* (Dec. 2021),

 $https://www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/0000000002\\ 66/Definition\%20Midwifery\%20Scope\%20of\%20Practice\_2021.pdf.$ 

NPWH and ACNM file this amicus brief in support of the Clinicians' argument that the APRN Restriction deprives Montanans of their fundamental right to seek abortion services from a qualified healthcare provider of their choice by preventing APRNs, who can safely and effectively provide abortions, from doing so.

Abortion is an extremely safe form of health care that falls well within APRNs' broad scope of practice, as determined by Montana regulations and national medical professional organizations. Indeed, abortions are safer and less complicated than many procedures that APRNs are authorized to perform and medications that APRNs are authorized to prescribe in Montana. Further, medical research confirms that APRNs provide abortion care as safely and effectively as licensed physicians. For these reasons, numerous national and global health and medical organizations strongly support the provision of abortion services by APRNs.

#### III. ARGUMENT

#### A. <u>Abortion Is An Extremely Safe Form Of Health Care</u>

Preventing APRNs from providing abortions advances no health or safety interest. Contrary to Appellants' claims about abortion risks, medication and aspiration abortions are among the safest procedures for women in the United States. See generally Ushma D. Upadhyay, Safety of Abortion in the United States,

Advancing New Standards in Reprod. Health, 2 (Dec. 2014),
https://www.ansirh.org/sites/default/files/publications/files/safetybrief12-14.pdf
(citing studies); Tracy A. Weitz & Diana Taylor et al., Safety of Aspiration

Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and
Physician Assistants Under a California Legal Waiver, 103 Am. J. Pub. Health
454, 456–57 (2013).

Abortions may be provided either through medication or by aspiration. Medication abortion typically involves the patient taking a first medication at a healthcare facility, and a second medication one to two days later at a location of her choosing, where she passes the pregnancy in a process similar to a miscarriage. *See* World Health Organization, *Safe Abortion: Technical and Policy Guidance for Health Systems* 3-4 (2d ed. 2012). Aspiration abortion, which can be performed on an outpatient basis, utilizes suction to remove the uterine contents and usually takes three to ten minutes to complete. *Id.* at 40–41.

The mortality rate of either method of abortion is extremely low. *See* Tara C. Jatlaoui et al., *Abortion Surveillance—United States*, 2015, 67 Morbidity & Mortality Weekly Rep. 1, 45 & tbl. 23 (2018) (finding mortality rate from 0.00052 to 0.00078% for approximate five-year periods from 1978 to 2014); Suzanne Zane et al., *Abortion-Related Mortality in the United States 1998-2010*, 126 Obstet. & Gynecol. 258, 261-62 (2015) (noting an approximate 0.0007% mortality rate);

National Academies of Sciences, Engineering, Medicine, *The Safety and Quality of Abortion Care in the United States*, at 74 (2018) (noting that the mortality rate of abortion is "a small fraction of that for childbirth").

Complications from either type of abortion are rare, with only 2.1% of patients, on average, experiencing any complications whatsoever. *See, e.g.*, National Academies of Sciences, Engineering, Medicine, *The Safety and Quality of Abortion Care in the United States*, at 10 (2018) ("The clinical evidence clearly shows that legal abortions in the United States . . . are safe and effective. Serious complications are rare."); Upadhyay, *Safety of Abortion in the United States*, *supra*, at 1. Abortion complication rates are similar to or lower than those associated with many other outpatient procedures, at 0.23% for major complications,<sup>2</sup> and only 1.88% for minor complications.<sup>3</sup> *See* Kari White et al.,

<sup>&</sup>lt;sup>2</sup> Major complications are defined as serious unexpected adverse events requiring hospital admission, surgery, or blood transfusion. Minor complications are defined as all other expected adverse events. Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 176 (2015).

<sup>&</sup>lt;sup>3</sup> Compared to the 0.23% rate for abortion, the major complication rate for colonoscopy is 0.24%. *See* Georgina Castro & M. Fuad Azrak et al., *Outpatient Colonoscopy Complications in the CDC's Colorectal Cancer Screening Demonstration Program: A Prospective Analysis*, 119 Cancer 2849, 2853 (2013). The overall complication rate for wisdom tooth extractions is nearly 7%. *See* François Blondeau & Nach G. Daniel, *Extraction of Impacted Mandibular Third Molars: Postoperative Complications and Their Risk Factors*, 73 J. Can. Dental Assoc. 325, 325 (2007). The overall complication rate for tonsillectomy is around 8-9%. *See* Jack L. Paradise & Charles D. Bluestone et al., *Tonsillectomy and* 

Complications from First-Trimester Aspiration Abortion: A Systematic Review of the Literature, 92 Contraception 422, 434 (2015); Upadhyay, Incidence of Emergency Department Visits, supra, at 179, 181. A 2015 study analyzing 2009-2010 data of 54,911 abortions found that only 0.03% involved an ambulance transfer to an emergency room on the day of the abortion. *Id.* at 180. These already low statistics actually may be overestimations of the complication rates because, compared to the general population, the Upadhyay study's sample pool consisted of low-income Medi-Cal beneficiaries, who likely have more health problems than the general population. *Id.* at 182. Only 0.87% of abortions resulted in an emergency room visit for an abortion-related complication within six weeks of the abortion. *Id.* at 178. When abortion-related complications do occur, they typically are minor, easily treatable, and can be safely managed by properly trained clinicians in an outpatient setting or by the patient at home. See id. at 175, 181.

In comparison, continuing with a pregnancy poses a greater risk to patients' overall physical health than obtaining an abortion. ACOG, *Practice Bulletin No. 183, Postpartum Hemorrhage*, 130(4) Obstet. & Gynecol. e168, e168 (2017)

Adenotonsillectomy for Recurrent Throat Infection in Moderately Affected Children, 110 Pediatrics 7, 7 (2002); Jose Granell & Pilar Gete et al., Safety of Outpatient Tonsillectomy in Children: A Review of 6 Years in a Tertiary Hospital Experience, 134 Otolaryngology – Head & Neck Surgery 383, 383 (2004).

(noting that postpartum hemorrhage may lead to adult respiratory distress syndrome, shock, abnormal blood clotting, acute renal failure, loss of fertility, and death). Indeed, the risk of maternal death associated with childbirth is about fourteen times higher than that associated with abortion. See ACOG, Committee Opinion No. 815, Increasing Access to Abortion, 136(6) Obstet. & Gynecol. e107, e108 (2020); ACOG, Practice Bulletin No. 222, Gestational Hypertension and Preeclampsia, 135(6) Obstet. & Gynecol. e237, e237 (2020) (noting that hypertensive disorders of pregnancy are a leading cause of maternal mortality worldwide); Ann Evensen et al., Postpartum Hemorrhage: Prevention and Treatment, 95(7) Am. Fam. Physician 442, 442 (2017) (noting that about 3-5% of obstetric patients will experience postpartum hemorrhage, the cause of 12% of U.S. maternal deaths); Elizabeth G. Raymond & David A. Grimes, *The* Comparative Safety of Legal Induced Abortion and Childbirth in the United States, 119 Obstet. & Gynecol. 215, 216 (2012). Moreover, the U.S. maternal mortality rate is higher than that in most other developed countries. See, e.g., Roosa Tikkanen et al., Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries, Commonwealth Fund (Nov. 18, 2020).

Despite Appellants' claims about the risks of medication abortion, App. Br. at 12, the pharmaceuticals typically used for medication abortion in the U.S.,

mifepristone and misoprostol, are no less safe than over-the-counter medications such as Tylenol. See, e.g., ACOG, ACOG Statement on Medication Abortion (Mar. 2016); National Women's Health Network, Safe, Online, Delivered: How to Get the Abortion Pill by Mail (Mar. 8, 2021), https://nwhn.org/safe-onlinedelivered-how-to-get-the-abortion-pill-by-mail; ACOG, Practice Bulletin No. 225, Medication Abortion Up to 70 Days of Gestation, 136(4) Obstet. & Gynecol. e31, e32 (2020). Both medications are approved by the U.S. Food and Drug Administration ("FDA") and supported by national and international major medical organizations. *Id.* at e31. Indeed, in 2021, the FDA eliminated a requirement that mifepristone be dispensed in person, finding that there was no material increase in serious safety risk from modifying the in-person requirement. Letter from Janet Woodcock, M.D., Acting Commissioner of Food and Drugs, FDA, to Maureen G. Phipps, MD, MPH, FACOG, CEO, ACOG (Apr. 12, 2021). Similarly, in October 2021, a University of California San Francisco research program, Advancing New Standards in Reproductive Health ("ANSIRH"), reviewed four U.S. studies on medication abortion without in-person clinician dispensing of mifepristone, and concluded that the mortality rate was 0% and that serious adverse events occurred in less than 1% of the cases. ANSIRH, U.S. Studies on Medication Abortion Without In-person Clinician Dispensing of *Mifepristone* (2021), at 1. Mifepristone and misoprostol are the same medications

used to manage miscarriage, which APRNs regularly handle. See Justin J. Chu & Adam J. Devall et al., Mifepristone and Misoprostol versus Misoprostol Alone for the Management of Missed Miscarriage (MifeMiso): a Randomised, Double-Blind, Placebo-Controlled Trial, 396 Lancet 770 (Sept. 12, 2020),

https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2931788-8.

In sum, both medication and aspiration abortion are extremely safe.

#### B. APRNs Are Qualified To Provide Abortion Care

Contrary to Appellants' assertions, APRNs' training and general scope of practice is expansive. The American Association of Nurse Practitioners ("AANP") and *amicus* ACNM, two professional organizations recognized by the Montana Board of Nursing, define APRNs' scope of practice broadly, leaving APRNs with great latitude to provide a wide range of services, including abortion. Moreover, APRNs routinely perform procedures and prescribe medications that are more complex than early abortion care. Unsurprisingly, numerous studies have established APRNs' ability to safely and effectively provide abortion care.

# 1. APRNs Are Authorized to Provide Health Care That Is Similar to or More Complex than Early Abortion Care

APRNs licensed by the Board of Nursing in Montana provide a broad range of health care, including care that is similar to or significantly more complex than early abortion. To obtain an APRN license in Montana, an applicant must complete a graduate-level education program, hold an active registered nurse

license, and receive certification from a national professional organization. *See* Mont. Admin. R. 24.159.1412. Once licensed, an APRN may do the following:

[P]rovid[e] initial, ongoing, and comprehensive care, including: (i) physical examinations, health assessments, and/or other screening activities; . . . (iii) ordering durable medical equipment, diagnostic treatments and therapeutic modalities, laboratory imaging and diagnostic tests, and supportive services, including, but not limited to, home healthcare, hospice, and physical and occupational therapy; (iv) receiving and interpreting results of laboratory, imaging, and/or diagnostic studies; [and] (v) working with clients to promote their understanding of and compliance with therapeutic regimens.

Mont. Admin. R. 24.159.1406(1)(b). The Montana Board of Nursing also grants APRNs prescriptive authority (*i.e.*, the ability to prescribe medications) after they meet certain additional educational requirements, *see* Mont. Code Ann. § 37-8-202(1)(h); Mont. Admin. R. 24.159.1463(2)–(3), permitting them to "prescribe, procure, administer, and dispense . . . controlled substances pursuant to applicable state and federal laws and within the APRN's role and population focus," Mont. Admin. R. 24.159.1461(1). The broad list of permissible practices for APRNs is inclusionary rather than exclusionary. Thus, Montana's requirement that an APRN must practice consistent with "the role and population focus in which the APRN has current national certification," Mont. Admin. R. 24.159.1406(1), serves as the appropriate limit on APRN practice.

The Montana Board of Nursing recognizes a number of national professional organizations that outline the scope and standards of practice for APRNs, including the AANP and the ACNM. *See Montana Board of Nursing Recognized National Professional Organizations (NPO) for APRN Scope and Standards of Practice*, Mont. Dep't of Lab. & Industry (Aug. 2018), http://boards.bsd.dli.mt.gov/Portals/133/Documents/nur/aprn\_sop\_documents.pdf.

Like the Montana Board of Nursing, none of these organizations provide a comprehensive or exhaustive list of health care that APRNs are authorized to provide.

The AANP, for example, instructs that "[a]s licensed, independent practitioners, . . . NPs provide *a wide range of* health care services including the diagnosis and management of acute, chronic, and complex health problems, health promotion, disease prevention, health education, and counseling to individuals, families, groups and communities." *Scope of Practice for Nurse Practitioners*, Am. Ass'n of Nurse Practitioners (2019), https://www.aanp.org/advocacy/advocacy-resource/position-statements/scope-of-

practice-for-nurse-practitioners (emphasis added). To that end, "NP practice *includes, but is not limited to*, assessment; ordering, performing, supervising and interpreting diagnostic and laboratory tests; making diagnoses; initiating and

managing treatment including prescribing medication and non-pharmacologic treatments . . . . " *Id.* (emphasis added).

Similarly, amicus ACNM broadly defines the scope of practice for certified nurse-midwives as "encompass[ing] the independent provision of care during pregnancy, childbirth, and the postpartum period; sexual and reproductive health; gynecologic health; and family planning services, including preconception care." Definition of Midwifery and Scope of Practice of Certified Nurse-Midwives and Certified Midwives, Am. C. of Nurse-Midwives (Dec. 2021, https://www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/000000002 66/Definition%20Midwifery%20Scope%20of%20Practice\_2021.pdf. Nursemidwives may "conduct physical examinations; independently prescribe medications . . .; admit, manage and discharge patients; order and interpret laboratory and diagnostic tests; and order medical devices, durable medical equipment, and home health services." Id. Based on the standards of practice defined by the AANP and ACNM, nurse practitioners and nurse-midwives are given considerable latitude regarding the medical services and care they may provide.4

<sup>&</sup>lt;sup>4</sup> The World Health Organization ("WHO"), an agency of the United Nations tasked with promoting the health of people internationally, recognizes the benefits of including abortion care in APRNs' scope of practice and has recommended against provider restrictions. World Health Organization, *Abortion Care Guideline* (2022), at 59, https://www.who.int/publications/i/item/9789240039483. According

APRNs may provide a broad range of medical services that is similar to early abortion care. For example, managing miscarriages, which is within APRNs' scope of practice, entails essentially the same health care as early abortion.

Miscarriages can be managed with medication, specifically misoprostol, one of the medications used in medication abortion. See Amy J. Levi & Tara Cardinal, Early Pregnancy Loss Management for Nurse Practitioners and Midwives, Women's Healthcare: A Clinical Journal for NPs (May 2016), https://npwomenshealthcare.com/early-pregnancy-loss-management-nurse-practitioners-midwives/. APRNs treating miscarriages may also perform an aspiration procedure—in which the cervix is dilated and a curette is used to remove

practitioners-midwives/. APRNs treating miscarriages may also perform an aspiration procedure—in which the cervix is dilated and a curette is used to remove the uterine contents through suction—which is essentially the same procedure required for early abortion. *Id*.

Further, APRNs provide health care services that are as or more complex than early abortion, including, but not limited to, neuraxial anesthesia, central line insertions, arterial line insertions, intubations, chest tube insertions, surgical first assistance, colonoscopy, and endoscopy. Some APRN-provided services require

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to the WHO, a systematic review of studies published between 2010 and 2019 "showed that restrictions on who can provide and manage abortion resulted in delays to and burdens in accessing abortions." *Id.* By contrast, expanding the range of abortion care providers provides a variety of benefits including improved timely access, reduced system costs, and prevention of unsafe self-management. *Id.* 

similar skills to those required in early abortion care, including inserting and removing intrauterine contraceptive devices ("IUDs") and other contraceptive implants, and performing endometrial biopsies. See, e.g., Courtney B. Jackson, Expanding the Pool of Abortion Providers: Nurse-Midwives, Nurse Practitioners, and Physician Assistants, Women's Health Issues 21-3S (2011) at S42, https://www.whijournal.com/action/showPdf?pii=S1049-3867%2811%2900011-9. Like aspiration abortion, inserting and removing an IUD involves placing an instrument through the cervix, and difficult removals may necessitate cervical dilation. See Aimee C. Holland & Brandi Shah et al., Preparing for Intrauterine Device Consults and Procedures, Women's Healthcare at 39 (Dec. 2020), https://www.npwomenshealthcare.com/wpcontent/uploads/2020/11/WHC1220 IUDConsultsProcedures.pdf. Finally, APRNs with a DEA license can prescribe controlled substances, which are potentially dangerous and addictive, and carry greater risk than the medications used in medical abortion. See U.S. Department of Justice, Diversion Control Division, Mid-Level Practitioners Authorization by State, https://www.deadiversion.usdoj.gov/drugreg/practioners/ (last visited Sept. 18, 2022).

#### 2. APRNs Provide Both Medication and Aspiration Abortions As Safely and Effectively As Physicians and Physician Assistants

Peer-reviewed studies demonstrate that APRNs provide both medication and aspiration abortions as safely and effectively as physicians and physician assistants. See Lydia Mainey & Catherine O'Mullan et al., The Role of Nurses and Midwives in the Provision of Abortion Care: A Scoping Review, J. of Clinical Nursing at 1 (Feb. 2020) (concluding that nurses and midwives can safely provide abortions based on systematic review of 74 published research and/or reports from 2008 to 2019 on the nursing or midwifery role in abortion care). In one study, researchers compared 5,812 aspiration procedures performed by physicians with 5,675 aspiration procedures performed by APRNs and physician assistants over a span of four years. See Weitz, supra, at 457. The APRNs and physician assistants participating in the study were newly trained to perform aspiration abortions, with an average of one and a half years' experience providing abortion care compared to the physicians' average of fourteen years' experience. Id. at 455. The study found that "care provided by newly trained NPs [Nurse Practitioners], CNMs, and PAs [Physician Assistants] was not inferior to that provided by experienced physicians." *Id.* at 458. With regard to major complications, the study found that there was no significant difference in terms of risk between provider groups. *Id.* at 459 ("Both provider groups had extremely low numbers of complications, less than 2% overall—well below published rates—and only 6 complications out of 11 487 procedures required hospital-based care . . . . [W]e conclude that the difference between the 2 groups of providers is not clinically significant."). The results "confirm[ed] existing evidence from smaller studies that the provision of abortion[s] by [nurse practitioners, certified nurse midwives, and physician assistants] is safe and from larger international and national reviews that have found these clinicians to be safe and qualified health care providers." *Id*.

Another study similarly found no significant difference in outcomes between provider types for first-trimester aspiration abortion followed by immediate IUD insertion. See Eva Patil & Blair Darney et al., Aspiration Abortion with Immediate Intrauterine Device Insertion: Comparing Outcomes of Advanced Practice Clinicians and Physicians, 61 J. Midwifery & Women's Health 325, 329 (2016). The study compared the outcomes of 445 procedures performed by physicians to 224 procedures performed by Advanced Practice Clinicians (i.e., nurse practitioners, certified nurse-midwives, and physician assistants) over the course of two years in Oregon. Id. at 326. Researchers determined that there were no clinically significant differences between physicians, APRNs and physician assistants as providers of first-trimester aspiration abortion followed by immediate

IUD insertion.<sup>5</sup> *Id.* at 329. Indeed, the WHO recommends that nurses and midwives share with physicians the task of managing abortion and post-abortion care in the first trimester, including both medication and aspiration abortions.

Caron Kim & Annik Sorhaindo et al., *WHO Guideline and the Role of the Physician in Task Sharing in Safe Abortion Care*, Vol. 63, Best Practice & Research Clinical Obstetrics & Gynaecology at 59-60 (Feb. 2020).

Similarly, studies have shown that APRNs provide medication abortions with the same safety, efficacy, and patient acceptability as physicians. In fact, some research shows that APRNs may provide medication abortions with *greater* efficacy and patient acceptability than physicians. *See* H. Kopp Kallner & R. Gomperts et al., *The Efficacy, Safety and Acceptability of Medical Termination of Pregnancy Provided by Standard Care by Doctors or by Nurse-midwives: A Randomised Controlled Equivalence Trial*, 122 BJOG: An Int'l J. of Obstetrics and Gynaecology 510, 515 (2014). The study found that 99% of the women treated by nurse-midwives did not require further intervention (*i.e.*, follow-up aspiration to

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<sup>&</sup>lt;sup>5</sup> The results of both studies align with research from multiple countries confirming that APRNs can safely provide abortion care. *See, e.g.*, Shireen J. Jejeebhoy & Shveta Kalyanwala et al., *Can Nurses Perform Manual Vacuum Aspiration (MVA) As Safely and Effectively As Physicians? Evidence From India*, 84 Contraception 615, 620 (2011); Ina Warriner et al., *Rates of Complication in First-Trimester Manual Vacuum Aspiration Abortion Done by Doctors and Mid-level Providers in South Africa and Vietnam: A Randomised Controlled Equivalence Trial*, 368 Lancet 1965, 1971 (2006).

complete the abortion), and 95.8% experienced no complications following the medication abortion (compared to 97.4% and 93.5%, respectively, for women treated by physicians). *Id.* at 514. Moreover, women that met with nurse-midwives were significantly more likely to express a preference for nurse-midwives if they ever required another medication abortion. *Id.* 

Medical research confirms that APRNs can competently and effectively administer abortion care.

# C. <u>Medical And Public Health Groups Support The Provision Of</u> <u>Abortions By APRNs</u>

Major medical and public health groups support the provision of abortions by APRNs as a means of providing greater access to qualified healthcare providers. The American Public Health Association ("APHA") is a professional organization of public health professionals dedicated to addressing public health issues and public health policies backed by science. APHA recommends that appropriately trained and competent nurse practitioners and certified nurse-midwives be permitted to provide medication and aspiration abortion. *See Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants*, Am. Pub. Health Ass'n (Nov. 1, 2011), https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/28/16/00/provision-of-abortion-care-by-advanced-practice-nurses-and-physician-assistants. APHA notes that the Institute of Medicine Committee on the Future of Primary Care and the Patient

Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (known together as the Affordable Care Act of 2010) have defined NPs and CNMs, along with generalist physicians and PAs, as primary care clinicians—indicating that these clinicians "are well positioned within the health care system to address women's needs for comprehensive primary care and preventive reproductive health services that include abortion care." *Id.* 

The American College of Obstetricians and Gynecologists ("ACOG") is a professional organization of physicians specializing in obstetrics and gynecology that supports women's health care through advocacy in federal and state legislatures. Appellants reference ACOG in their opening brief repeatedly, and make particular note of the ACOG recommendation that "clinicians who wish to provide medical abortion services should either be trained in surgical abortion services or should be able to refer to a clinician trained to provide surgical abortions." App. Br. at 12. In making this recommendation, however, ACOG made clear that it "supports . . . clinical training for residents and advanced practice clinicians in abortion care in order to increase the availability of trained abortion providers." ACOG, Committee Opinion No. 612, Am. C. of Obstetricians and Gynecologists (Nov. 2014) (reaffirmed 2022), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Abortion-Training-and-Education. Moreover, in

recommending that health care providers "be able to refer to a clinician trained to provide surgical abortion," ACOG made clear that it was not recommending that only clinicians trained to provide surgical abortion be permitted to provide medical abortion services. ACOG also has called "for the cease and repeal of legislation that creates barriers to abortion access," including the cease and repeal of "requirements that only physicians or obstetrician-gynecologists may provide abortion care…." ACOG Committee Opinion No. 815, Increasing Access to Abortion, supra, at e107.

The American Medical Women's Association ("AMWA") is an organization that functions at the local, national, and international level to advance women in medicine and improve women's health, by providing and developing leadership, advocacy, education, expertise, mentoring, and strategic alliances. AMWA has pledged to "work to increase the number of abortion providers by supporting initiatives to improve and increase training for medical students, residents and physicians in the full range of abortion procedures, and to add adequately trained Nurse-Midwives, Nurse Practitioners and Physician Assistants to the pool of potential abortion providers." *Position Paper on Principals of Abortion & Access to Comprehensive Reproductive Health Services*, Am. Med. Women's Ass'n, https://www.amwa-doc.org/wp-content/uploads/2018/05/Abortion-and-Access-to-Comprehensive-Reproductive-Health-Services.pdf.

The positions of these groups reflect and support what organizations representing APRNs have long asserted in terms of APRNs' ability to provide abortion care. In 1991, for example, the National Association of Nurse Practitioners in Women's Health (formerly National Association of Nurse Practitioners in Reproductive Health, or "NANPRH")—an association of women's health-focused nurse practitioners advocating for improved access and quality of health care for women—adopted a policy resolution acknowledging the provision of abortion care as within nurse practitioners' scope of practice: "Let it be resolved that NANPRH believes that nurse practitioners, with appropriate preparation and medical collaboration, are qualified to provide abortions." National Association of Nurse Practitioners in Women's Health, Resolution on Nurse Practitioners as Abortion Providers at 3 (Oct. 1991) https://5aa1b2xfmfh2e2mk03kk8rsxwpengine.netdna-ssl.com/wp-content/uploads/CNM\_NP\_PA\_org\_statements.pdf.

Similarly, in 2019, amicus ACNM updated and approved a position statement on "Midwives as Abortion Providers" that affirmed that "[m]anual vacuum aspiration abortion and medication abortion may be safely provided by trained advance practice clinicians (APCs), including midwives." *Midwives as Abortion Providers*, Am. C. of Nurse-Midwives (2019), at 1,

http://www.midwife.org/acnm/files/

acnmlibrarydata/uploadfilename/00000000314/PS-Midwives-as-Abortion-Providers-FINAL-August-2019.pdf.

The views of the professional medical organizations above are shared by global health organizations. Since at least 2012, the WHO, an agency of the United Nations tasked with promoting the health of people internationally, has been emphasizing the importance of having non-physician medical professionals (like the Clinicians) provide abortion care. In a policy guidance paper citing heavily to medical studies, the WHO noted that "[s]ince the advent of vacuum aspiration and medical abortion, [] abortion can be safely provided by a wide range of health workers in diverse settings" and recommended that midwives and nurses deliver both vacuum aspiration at up to 14 weeks gestational age and medical abortion using mifepristone plus misoprostol, or misoprostol alone, at up to 12 weeks gestational age. World Health Organization, Abortion Care Guideline, supra, at 59. The WHO has also noted that "[c]omparative studies have shown no difference in complication rates between women who had first-trimester abortions with MVA [manual vacuum aspiration] performed by midlevel health-care providers and those who had the procedure performed by a physician." World Health Organization, *Abortion Care Guideline*, supra, at 72.

The message of these organizations is clear: the provision of abortion services falls well within the scope of practice of APRNs, and APRNs are

competent to provide abortion care. These professional and public health organizations recommend, as a matter of promoting women's health, that APRNs be allowed to provide abortion care. This support stands in stark contrast to the supposed safety concerns underlying the APRN Restriction.

#### IV. CONCLUSION

Qualified APRNs, including certified nurse practitioners and certified nurse-midwives such as the Clinicians, should not be barred from providing abortion care in Montana. Like physicians and physician assistants, APRNs are able to provide abortion care safely and effectively. As such, the APRN Restriction unnecessarily restricts Montanans' access to abortion care and qualified healthcare providers' professional right to provide this care.

Dated: September 23, 2022 Respectfully submitted,

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#### **CERTIFICATE OF COMPLIANCE**

I hereby certify that the foregoing BRIEF FOR THE NATIONAL

ASSOCIATION OF NURSE PRACTITIONERS IN WOMEN'S HEALTH AND

THE AMERICAN COLLEGE OF NURSE-MIDWIVES AS AMICI CURIAE is proportionately spaced in 14-point roman, non-script text and contains 4,352 words excluding the brief's cover, table of contents, table of authorities, certificate of compliance, and certificate of service.

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