UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*.	Case No.: 6:25-cv-01491-DCJ-DJA Judge David C. Joseph Magistrate Judge David J. Ayo

PLAINTIFFS STATE OF LOUISIANA AND ROSALIE MARKEZICH'S MOTION FOR PRELIMINARY RELIEF UNDER 5 U.S.C. § 705

Plaintiffs State of Louisiana and Rosalie Markezich respectfully move under 5 U.S.C. § 705 for an order staying or postponing the effective date of the 2023 Risk Evaluation and Mitigation Strategy that the U.S. Food & Drug Administration (FDA) issued to allow mifepristone to be dispensed remotely (the 2023 REMS). Plaintiffs also move in the alternative under 5 U.S.C. § 705 for a preliminary injunction under Rule 65 of the Federal Rules of Civil Procedure ordering FDA to suspend or withdraw the 2023 REMS while this case proceeds.

The 2023 REMS is unlawful for at least the following reasons:

First, as five Fifth Circuit judges already have indicated, the 2023 REMS is arbitrary and capricious and an abuse of discretion in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). *All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 2913725, at *17–18 (5th Cir. Apr. 12, 2023) (*Alliance I*); *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 249–51 (5th Cir. 2023) (*Alliance II*), *rev'd and remanded on other grounds*, 602 U.S. 367 (2024) (*Alliance*). That is because FDA permanently removed the in-person dispensing requirement and made other changes based on sources that the agency conceded did not support its decision.

Second, the 2023 REMS is "otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Under 18 U.S.C. § 1462, Congress prohibits the use of "any express company or other common carrier or interactive computer service" for "any drug, medicine, article, or thing designed, adapted, or intended for producing abortion." Because a federal agency cannot permit what federal law expressly prohibits, FDA lacked authority to permanently remove the in-person dispensing requirement.

For these reasons, and as set forth fully in Plaintiffs' Complaint and supporting Memorandum of Law, interim relief is necessary and appropriate to mitigate irreparable injuries caused by the 2023 REMS. Interim relief will serve the public interest and will not harm Defendants.

This Motion is made on the grounds specified in this Motion, the accompanying Memorandum of Law, the exhibits attached to this Motion, the Complaint, and the Complaint's accompanying exhibits, as well as on such other and further oral or documentary evidence as may be presented to the Court at or before a hearing on this Motion.[1] An exhibit list and a proposed order are attached.

CONCLUSION

Under 5 U.S.C. § 705, the Court should enter an order against Defendants, including their employees, agents, successors, and all persons in active concert or participation with them, in which the Court:

1. Stays or postpones the effective date of the 2023 REMS while this case proceeds, and ensures that the "[t]he in-person dispensing requirement[ ], and FDA's obligation to enforce [it], will continue to apply," *Alliance II*, 78 F.4th at 254, or

2. Issues a preliminary injunction ordering Defendants to withdraw or suspend the 2023 REMS and to restore the in-person dispensing requirement while this case proceeds.

[1] Because the injunctive relief requested would serve the public interest, Plaintiffs ask the Court to exercise its discretion to not require a security or bond under Fed. R. Civ. P. 65(c). *See City of Atlanta v. Metro. Atlanta Rapid Transit Auth.*, 636 F.2d 1084, 1094 (5th Cir. 1981).

Respectfully submitted this 17th day of December, 2025.

s/ Michael T. Johnson
Michael T. Johnson (Lead)
LA Bar No. 14401
JOHNSON, SIEBENEICHER & INGRAM
2757 Highway 28 East
Pineville, LA 71360
Telephone: (318) 484-3911
Facsimile: (318) 484-3585
mikejohnson@jslawfirm.com

Counsel for Plaintiff Rosalie Markezich

Erin M. Hawley
WDLA Temp. Bar No. 918597
Erik C. Baptist
WDLA Temp. Bar No. 918596
Julie Marie Blake
WDLA Temp. Bar No. 918094
Frank W. Basgall
WDLA Temp. Bar No. 918593
Gabriella M. McIntyre
WDLA Temp. Bar No. 918594
Dalton A. Nichols
WDLA Temp. Bar No. 918595
ALLIANCE DEFENDING FREEDOM 44180
Riverside Parkway
Lansdowne, VA 20176
Telephone: (571) 707-4655
ehawley@ADFlegal.org
ebaptist@ADFlegal.org
jblake@ADFlegal.org
fbasgall@ADFlegal.org
gmcintyre@ADFlegal.org
dnichols@ADFlegal.org

Counsel for Plaintiffs State of Louisiana and Rosalie Markezich

s/ Caitlin Huettemann
LIZ MURRILL
Attorney General
J. Benjamin Aguiñaga*
Solicitor General
Caitlin Huettemann (Lead)
Assistant Solicitor General
LA Bar No. 40402
OFFICE OF THE LOUISIANA ATTORNEY GENERAL
1885 N. Third Street
Baton Rouge, LA 70804
Telephone: (225) 326-6766
AguinagaB@ag.louisiana.gov
HuettemannC@ag.louisiana.gov

Counsel for Plaintiff State of Louisiana

*pro hac vice forthcoming

CERTIFICATE OF CONFERENCE

I hereby certify that, pursuant to Local Rule 7.4.1, counsel conferred in good faith regarding the relief sought in this Motion. Defendants oppose Plaintiffs' Motion.

s/ Caitlin Huettemann
Caitlin Huettemann

EXHIBIT 1

#WeCount Report April 2022 to June 2025 (Dec. 9, 2025)

#WeCount report, April 2022 to June 2025
Released: December 9, 2025

#WeCount is a reporting effort that aims to capture national shifts in abortion volume, by state and month, following the *Dobbs v Jackson Women's Health Organization* Supreme Court decision to overturn Roe v Wade. This report includes data from April 2022 to June 2025.

For media inquiries, please contact SFP@ConwayStrategic.com.

For questions about #WeCount and information on how to enroll your practice, please contact WeCount@SocietyFP.org.

Please use the citation below to cite this #WeCount report.

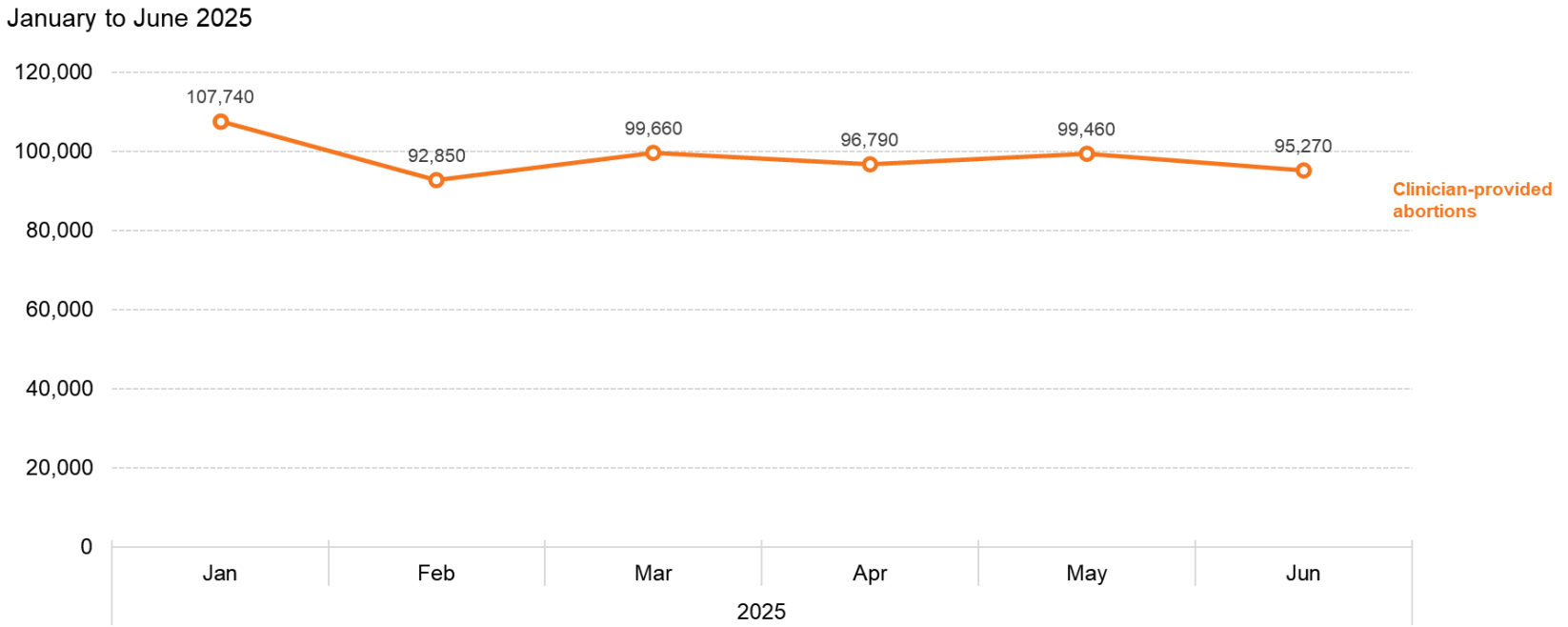
> *Society of Family Planning. #WeCount Report April 2022 through June 2025. 9 Dec. 2025, https://societyfp.org/wecount-report-10-june-2025-data/, https://doi.org/10.46621/750591yxmcwh.*

Key findings

- The number of abortions in the US healthcare system **continued to increase**, but with a smaller increase than in previous years.
- The monthly average number of abortions was **slightly higher in the first half of 2025** than the monthly average was in 2024.
- Nationally, the majority of abortions still occurred **in-person**.
- The number of abortions delivered via **telehealth has continued to increase**.
- In the first half of 2025, **27%** of all abortions within the US healthcare system were provided via telehealth.
- **Shield laws** continue to facilitate abortion access, with nearly 15,000 abortions per month provided under shield laws by June 2025.

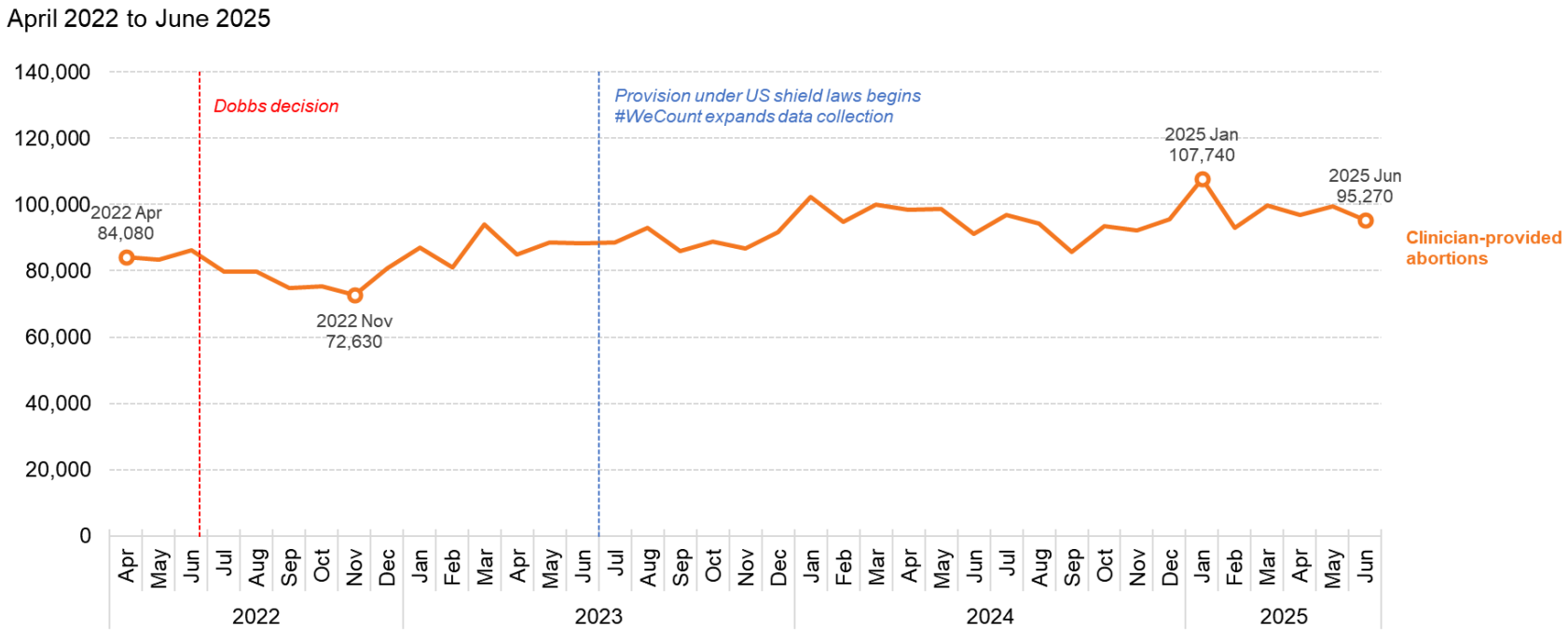
National findings

US abortions totaled 591,770 in the first six months of 2025



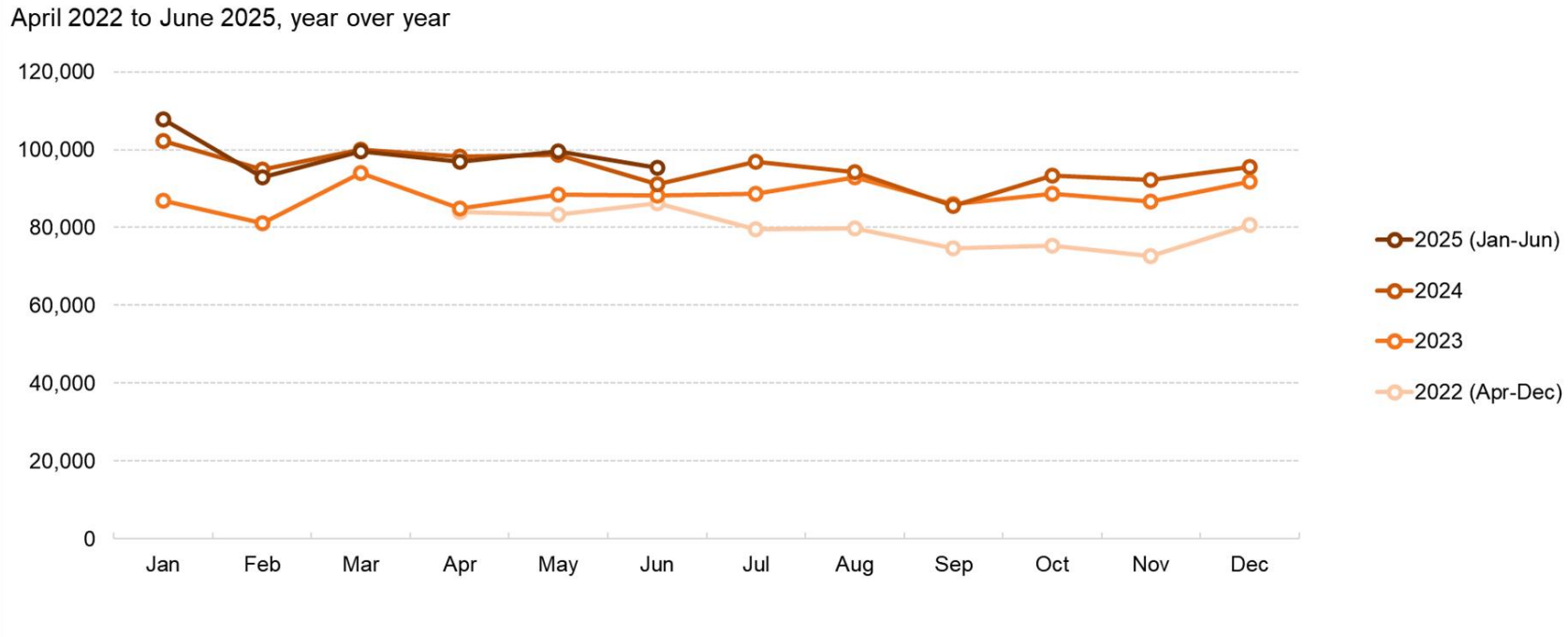
This #WeCount report includes new data for the first 6 months of 2025, when a total of 591,770 abortions were provided in the US healthcare system.

Abortions in the US have increased since *Dobbs*



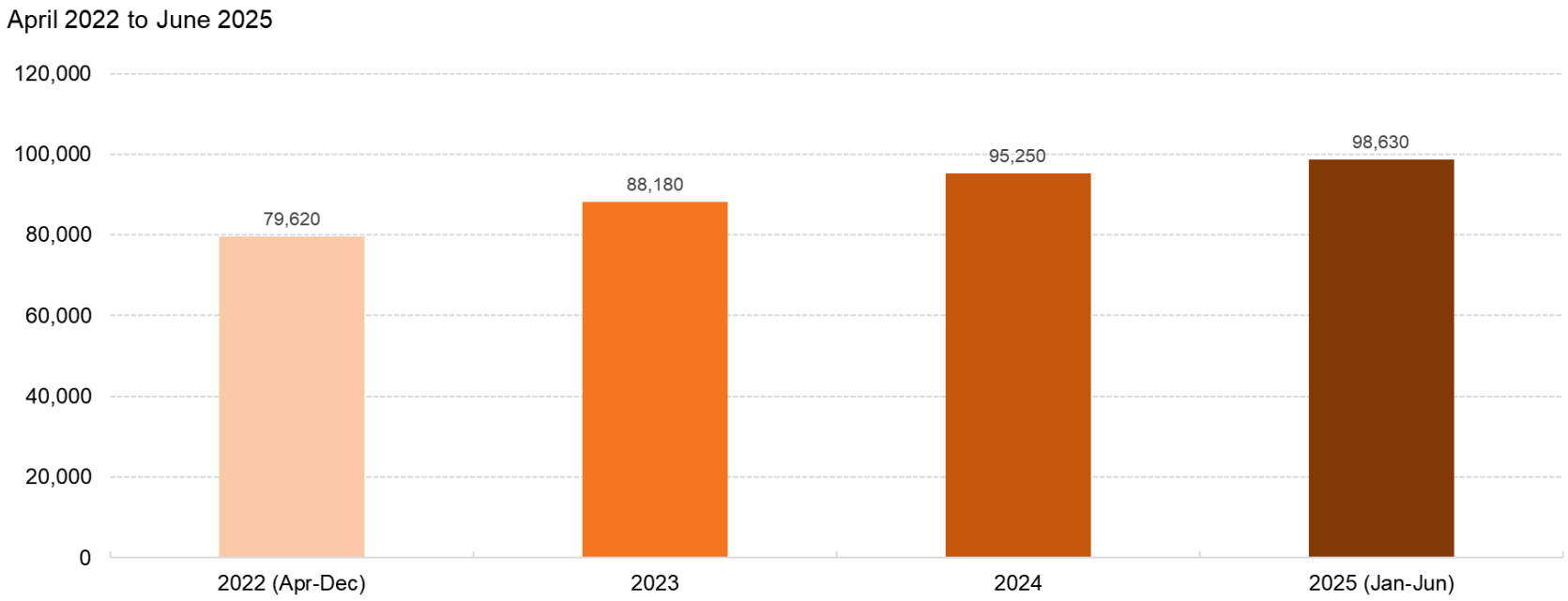
The monthly number of abortions increased gradually over time in the US since 2022. The monthly total peaked in January 2025 for the entire duration of #WeCount, reaching 107,740 abortions in a single month.

Abortion volume fluctuates from month to month, and has increased year-over-year



In addition to some monthly fluctuation, abortion volume is also increasing year-over-year, with 2025 monthly numbers only slightly higher than 2024.

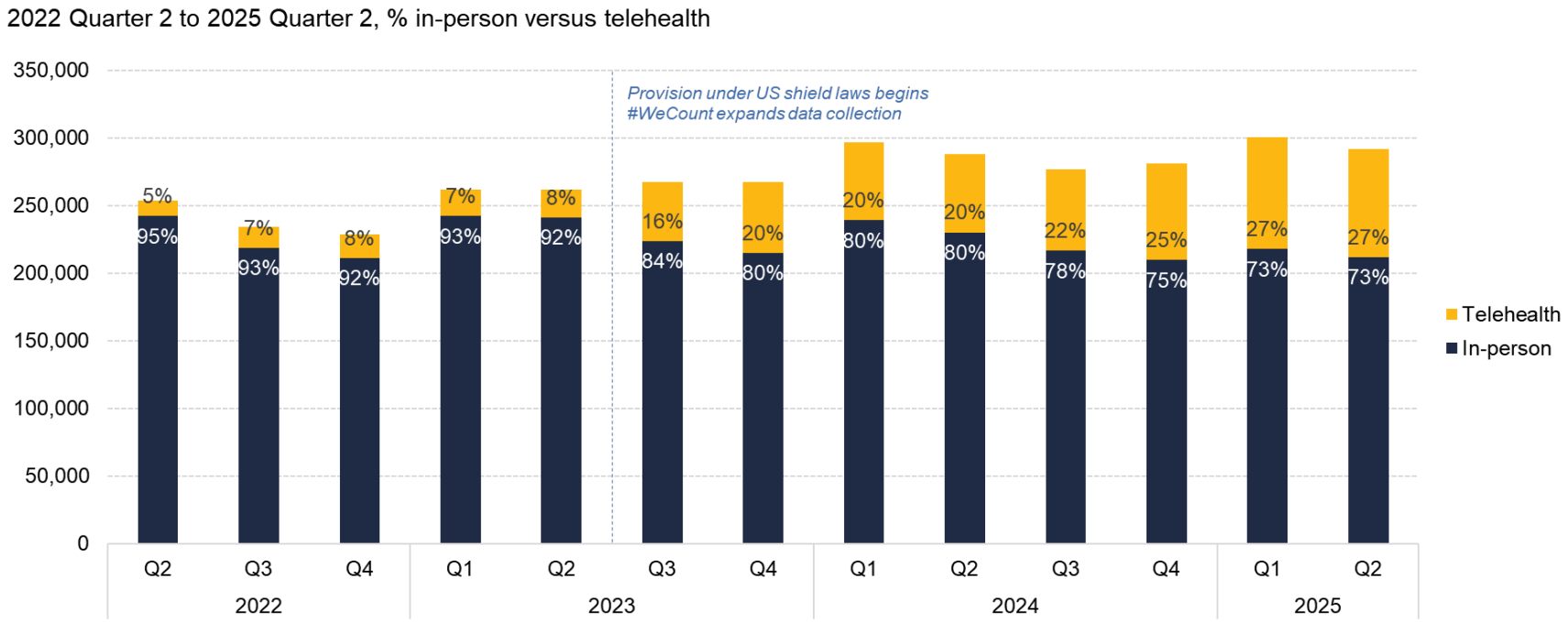
Monthly average numbers of abortions increased each year



The monthly average number of abortions climbed from 79,600 in 2022, to 88,200 in 2023, to 95,300 in 2024, to 98,800 in 2025. Note that the 2022 and 2025 monthly averages reflect partial years of data.

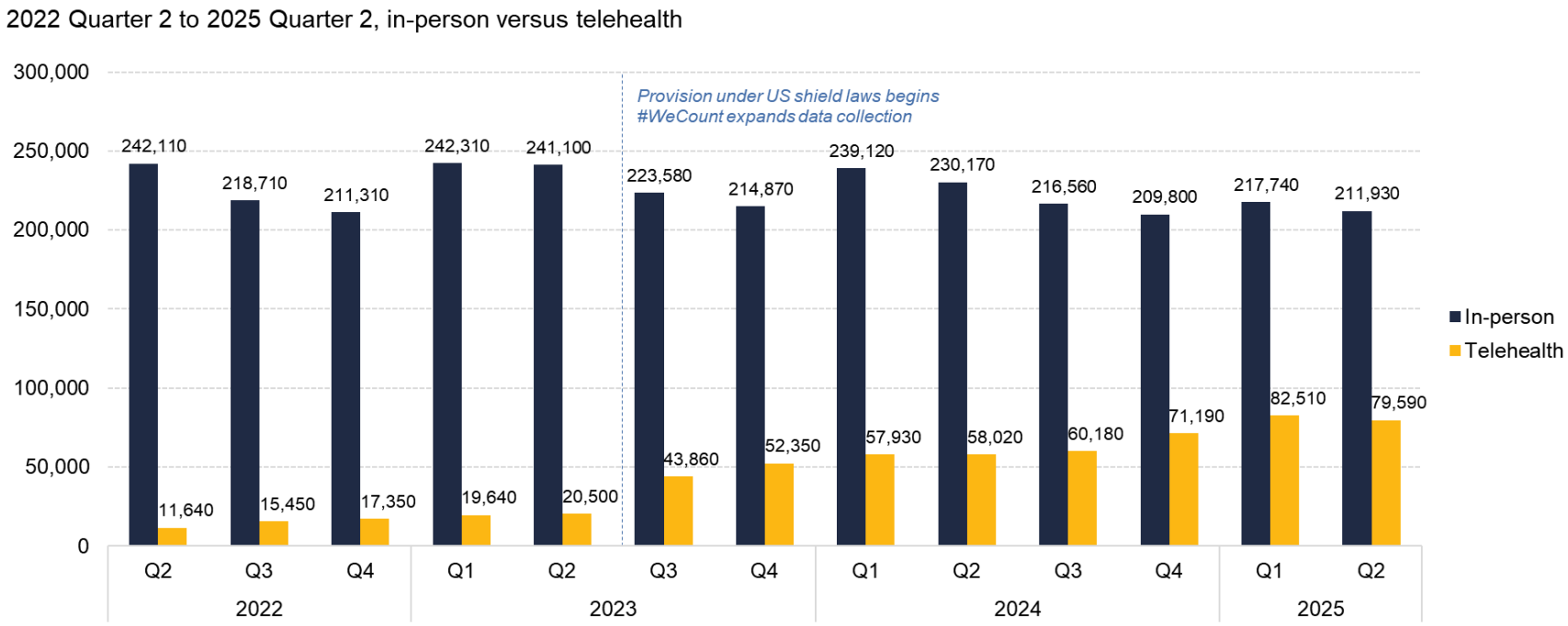
Telehealth findings

In the first six months of 2025, 27% of abortions were provided via telehealth



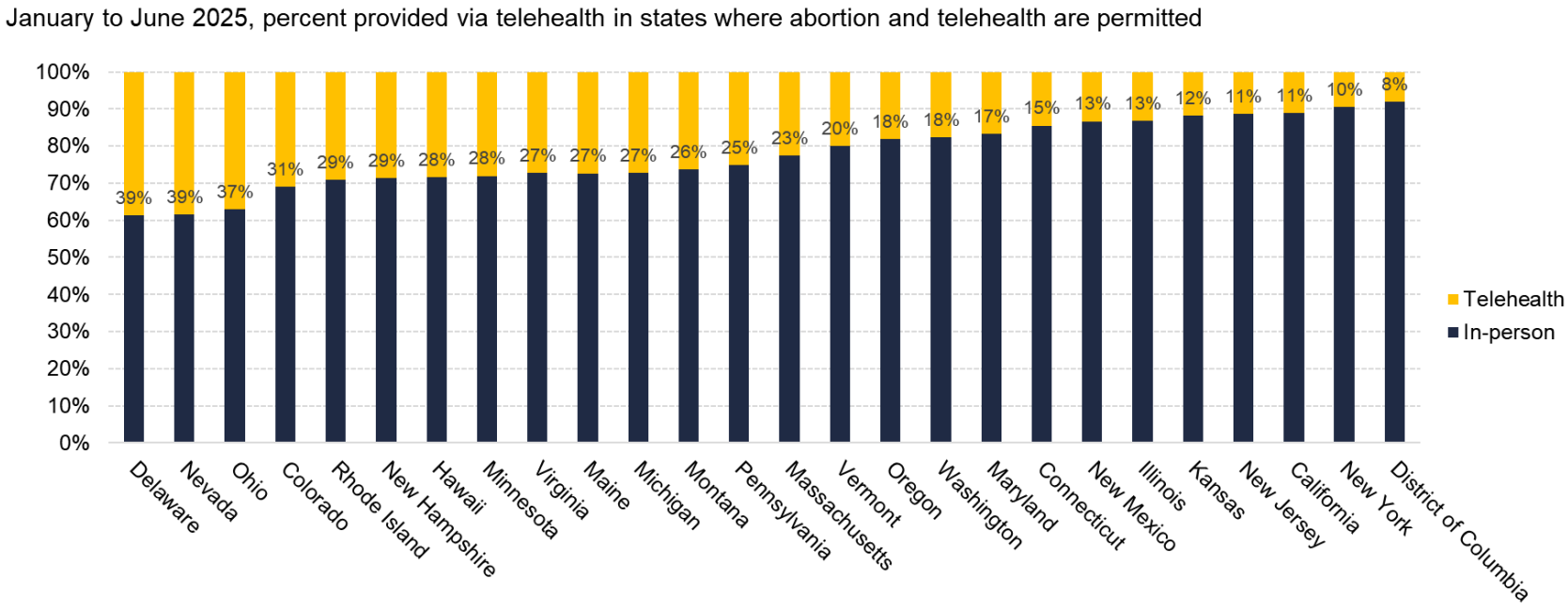
The proportion of abortions that were provided via telehealth increased over time from 5% in Quarter 2 of 2022 to 27% by Quarter 2 of 2025.

In-person abortion care declined slightly, while telehealth grew



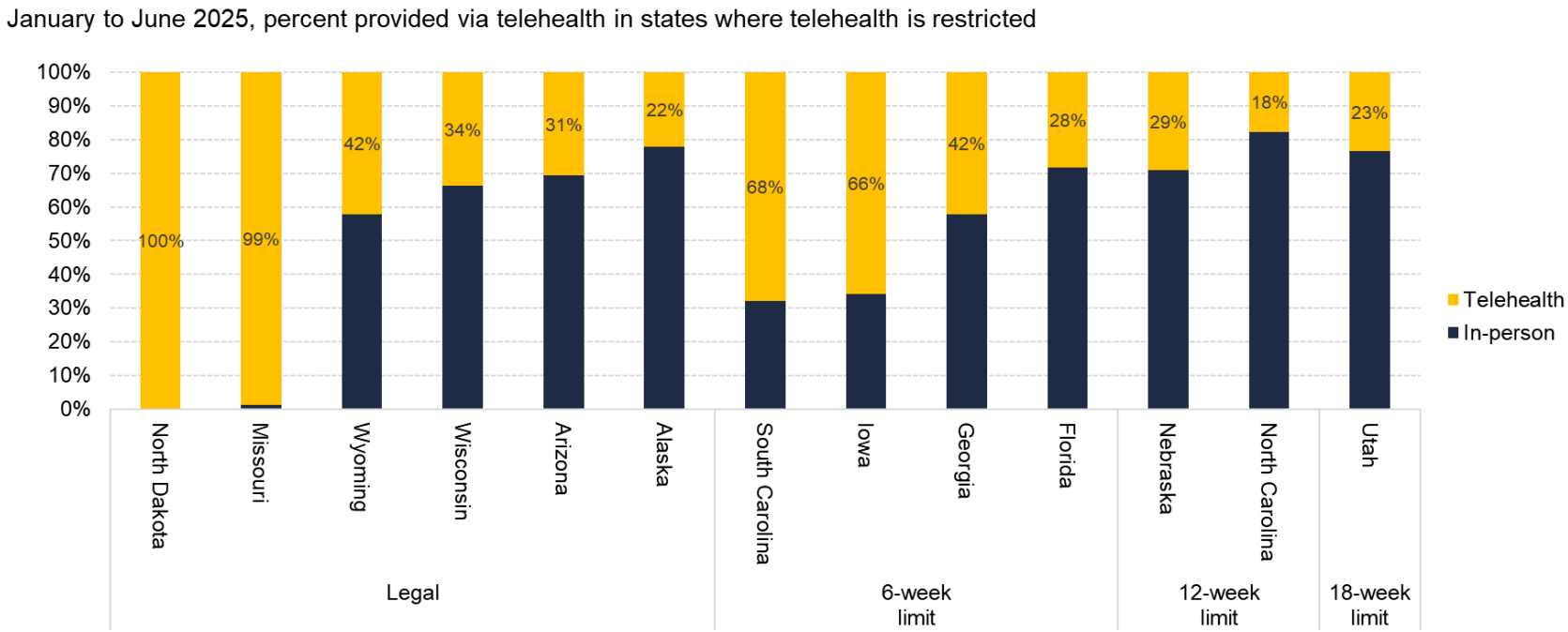
Telehealth abortion care (which involves mailing medication abortion pills) increased both in proportion and in absolute numbers over the study period. In-person abortion care (which includes both procedural abortions and medication abortion pills dispensed in person), was much more common than telehealth abortion. As telehealth has grown, the number of in-person abortions has not declined commensurately. The number of in-person abortions was lower in the second half of each year compared to the first half.

Where abortion and telehealth are permitted, the share of abortions provided via telehealth varied widely



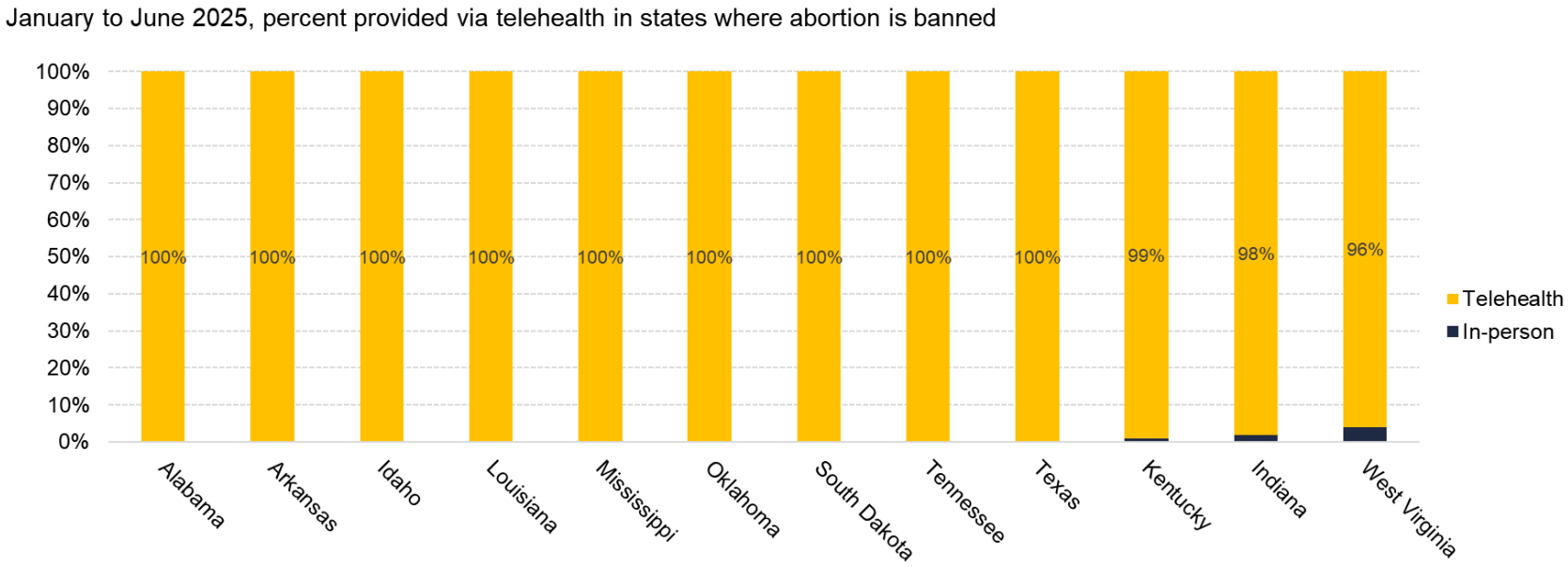
Across the US, in states that permit abortion and telehealth provision of abortion, there was substantial variation in the proportion of abortions provided via telehealth, ranging from 8% to 39%. In several larger states (eg, California, New Jersey, and New York), telehealth represents a smaller share of abortions, at about 9-13% of all abortions.

Where telehealth abortion is restricted, the share of abortions provided via telehealth under shield laws varied widely



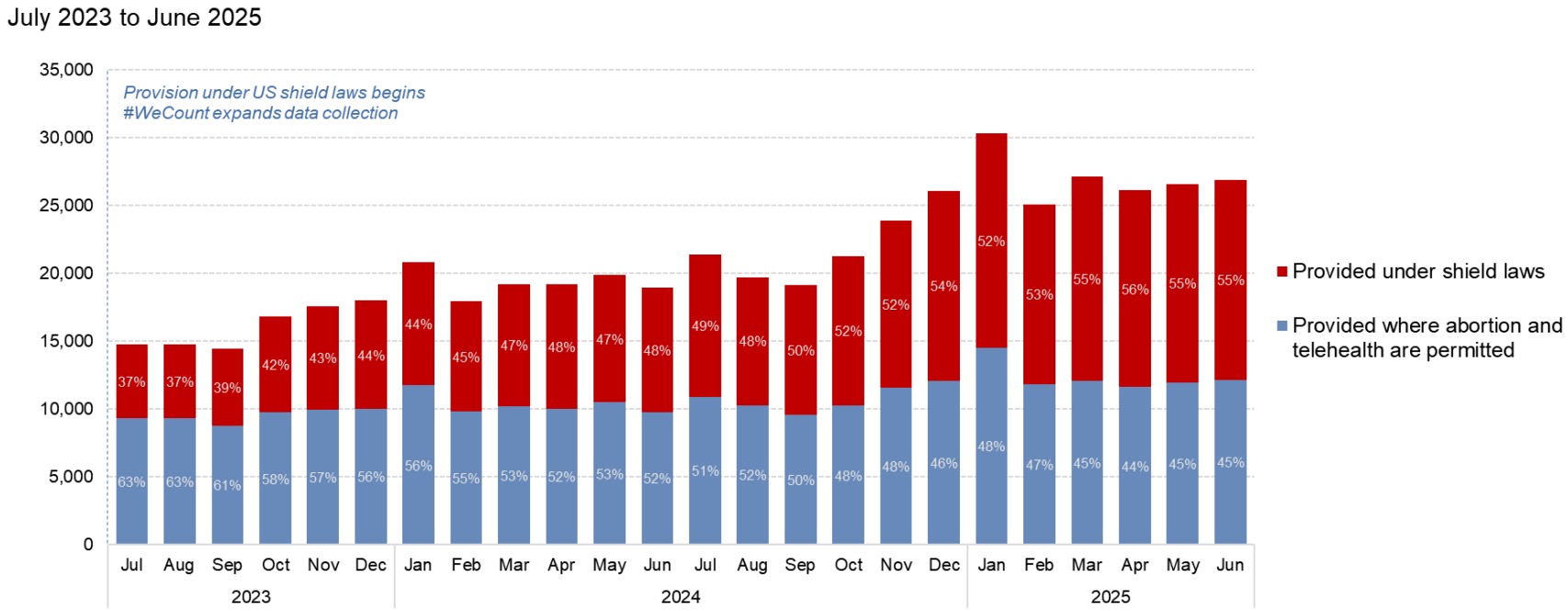
In states where abortion is permitted but telehealth is restricted, including states with 6, 12, and 18-week bans, the proportion of abortions provided by telehealth varies widely. In North Dakota, no abortion facilities were providing in-person care from January to June 2025.

Where abortion is banned, nearly all abortions were provided via telehealth under shield laws



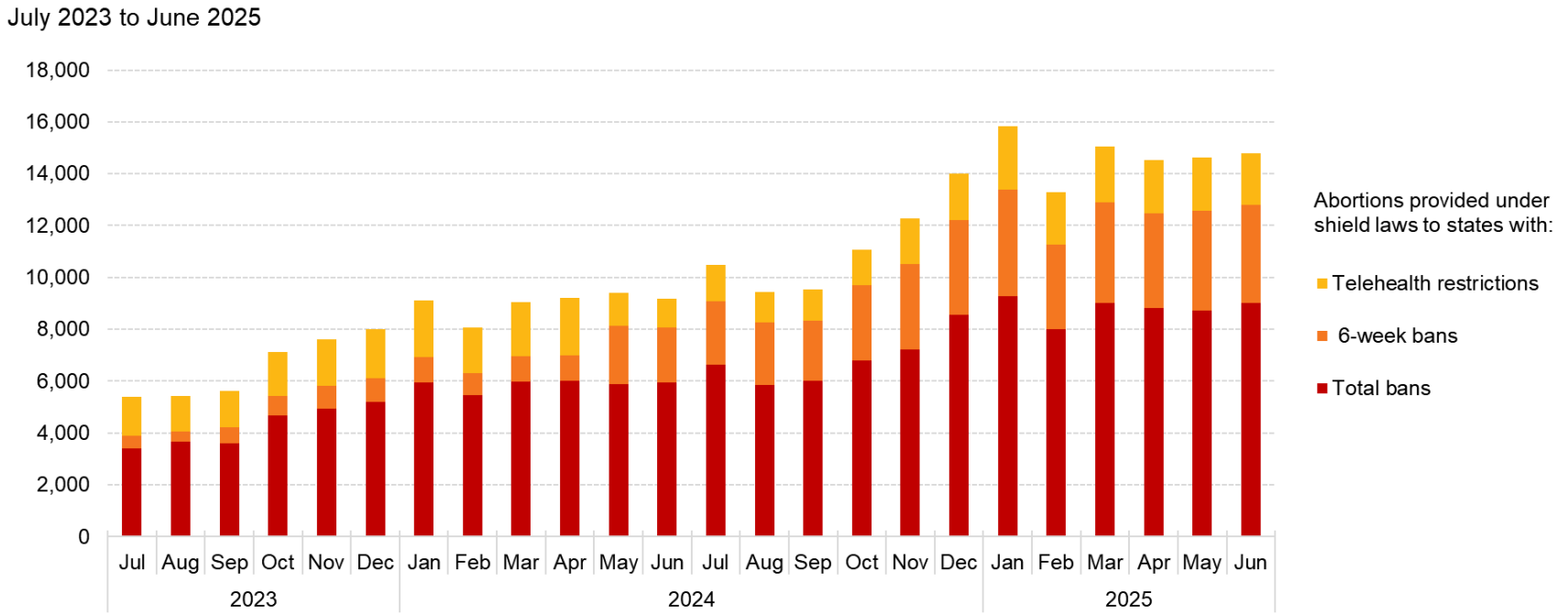
In states with total abortion bans, telehealth abortions provided under shield laws make up nearly all abortions occurring within those states. Residents may travel to other states to obtain care. Abortion provided in person under exceptions are represented in dark blue, making up 2% of abortions in Indiana and 4% of abortions in West Virginia.

A growing share of telehealth abortions are provided under shield laws



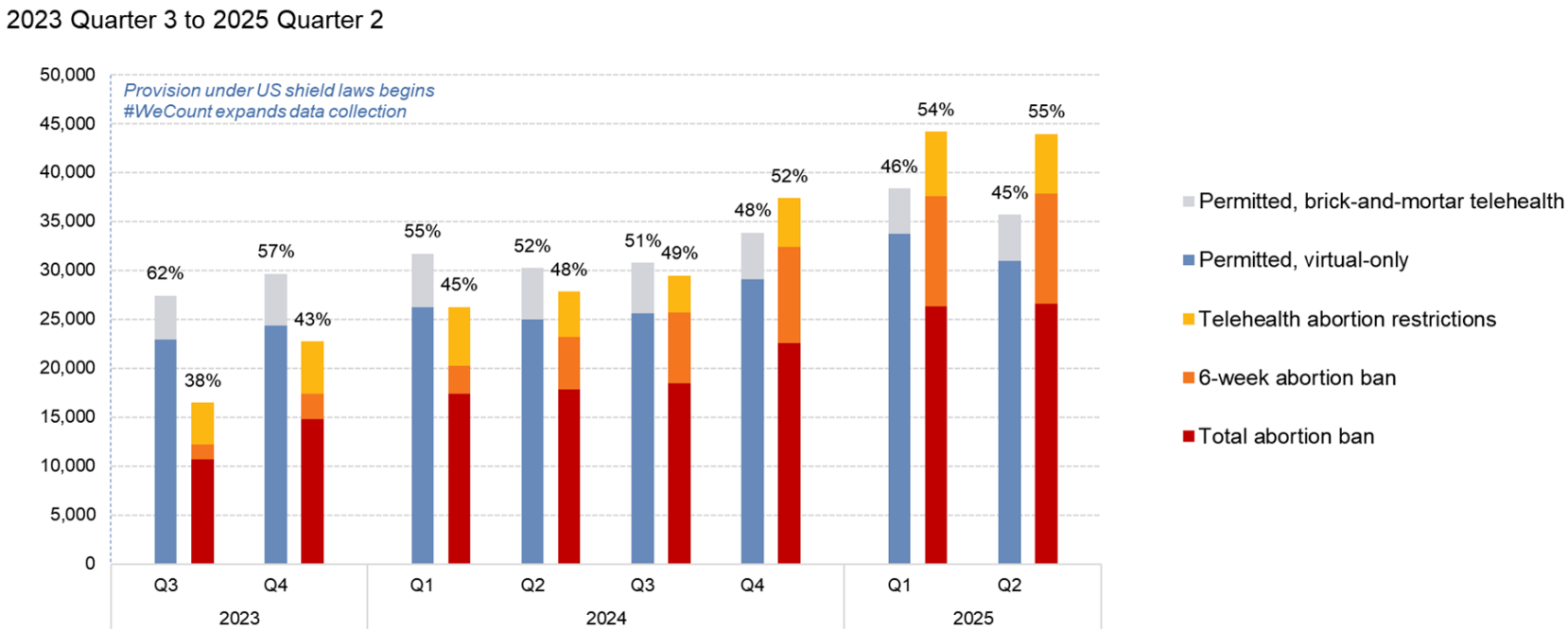
The number and proportion of telehealth abortions provided under shield laws has increased over time. As of June 2025, more than half (55%) of telehealth abortions are provided under shield laws.

Number of abortions provided via shield laws is increasing



By June 2025, abortions provided under shield laws totaled 14,770 per month. Shield laws provide protections for providers to mail medication abortion pills to people in states with telehealth restrictions, 6-week bans, and total abortion bans. The number of abortions provided under shield laws into states with these restrictions has increased since providers began to offer abortion under shield laws in July 2023, with notable increases in provision to states after enactment of 6-week bans and total abortion bans. Some of the increase in states with 6-week bans is due to changes in restrictions at the state-level, such as states that transitioned from having telehealth restrictions to having 6-week bans during this time period and thus switched categories.

Abortions provided under shield laws account for a growing share of all telehealth abortions



Telehealth abortions provided by virtual clinics (those that that are online only and have no brick-and-mortar clinic) to states that permit abortion and telehealth abortion have increased since 2023. Telehealth abortions provided by brick-and-mortar clinics have remained steady. Telehealth abortions provided to people in states with telehealth restrictions also remained relatively steady. Telehealth abortions provided to people in states with 6-week bans increased. Telehealth abortions provided to people living in states with total bans increased substantially in the first six months of 2025.

Background

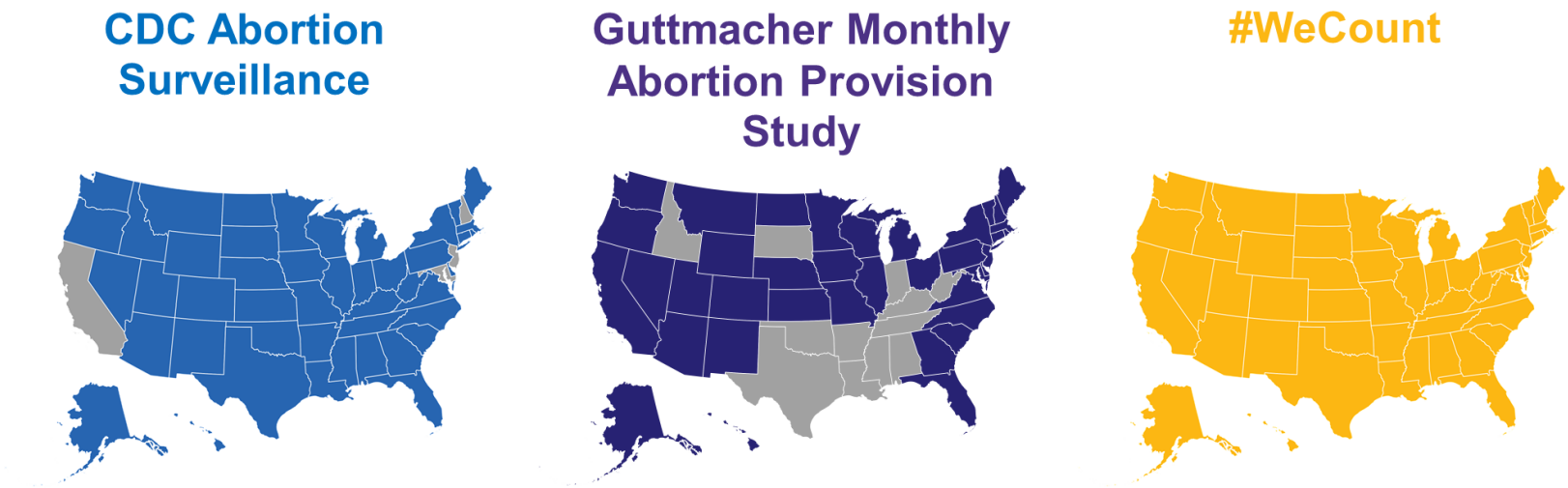
#WeCount is a national effort that aims to report the monthly number of abortions in the US, by state and month starting in April 2022. #WeCount data include clinician-provided abortions, defined in this report as medication or procedural abortions completed by a licensed clinician within the US in a clinic, private medical office, hospital, or virtual-only clinic. This report does not reflect any self-managed abortions, defined as ending a pregnancy outside the formal healthcare system, such as medications provided by community networks or websites that sell pills outside of the US healthcare system. These data reflect the status of abortion provision in the US and can be used by healthcare systems, public health practitioners, and policymakers so that their decisions can be informed by evidence.

#WeCount in context: the landscape of research efforts to count abortions

#WeCount is one of several efforts to capture changes in abortion volume in the US. Below, we outline the features of three of these initiatives, including their geographic reach, timing, the types of abortions included, and additional variables collected.

		#WeCount	Guttmacher Monthly Abortion Provision Study	CDC Abortion Surveillance
Timing	Reporting cadence every…	6 months	1 month	1 year (last 2022)
	Data interval	Monthly	Monthly	Annual
Type	Telehealth abortions to states where permitted	**Yes**	**Yes**	**Some**
	Abortions provided under shield laws to states with any legal abortion	**Yes**	**Yes**	No
	Abortions provided under shield laws to states with bans	**Yes**	No	No
	Abortions provided outside the formal healthcare system	No	No	No
Additional variables	Reports telehealth breakdown	**Yes**	No	No
	Abortion characteristics beyond counts	No	**Yes**	**Yes**

States reflected across efforts to count abortions



Terminology

Delivery settings

- **Brick and mortar clinic:** A physical clinic where a patient can go to receive care
- **Virtual-only clinic:** An online-only provider

Delivery methods

- **Brick-and-mortar telehealth:** Telehealth abortions offered by a brick-and-mortar clinic
- **In-person care:** Abortions in which a clinician meets with the patient face-to-face; can be procedural or medication abortions
- **Self-managed abortion:** Abortion using medications, herbs, or something else, or obtaining pills from friends or online without clinician assistance
- **Telehealth abortion:** Medication abortion offered by a clinician through remote consultation with the patient, resulting in remote dispensing of medications by mail

Types of care

- **Medication abortion:** Abortion performed with medications, including mifepristone, misoprostol, and misoprostol alone
- **Procedural abortion:** Abortion performed with instrumentation, including uterine aspiration (manual or electric), dilation and curettage, dilation and evacuation, or dilation and extraction

Legal context

- **Shield laws:** Legal protections put in place by some states to reduce legal risk for clinicians who offer abortions to patients in states where abortion is prohibited or severely restricted

Methods

In early 2022, #WeCount developed a database of all clinics, private medical offices, hospitals, and virtual clinic providers in the US known to offer abortion care. We started with the Abortion Facility Database from Advancing New Standards in Reproductive Health (ANSIRH) at University of California, San Francisco. Throughout the study period, we added new providers to our database as we became aware of them, using AbortionFinder.org and INeedanA.com to conduct regular searches in all 50 states and the District of Columbia. This report also includes abortions provided under shield laws by US-based licensed providers who are following their own state law. The Society provided compensation to participating facilities for each monthly submission.

The data in this report includes the monthly counts reported by providers for April 2022 through June 2025. From April 2022 to December 2024, 19% of abortions were imputed. From January to June 2025, 28% of abortions were imputed. The magnitude of imputation in each state is noted with symbols in the data tables. For providers that reported some months of data, we created a provider-level imputation for missing months. For these imputations, we calculated the average percent change in abortion volume in the state to impute values for the missing months. For providers that never reported to #WeCount, we imputed all months of data. To develop our imputations, we used information from news articles, contacts known to the non-reporting clinics, knowledge of the abortion volumes by state, or the median #WeCount number to determine the provider type. To compute medians, we categorized reporters to #WeCount into five types of facilities and calculated the median for April and May 2022 for each category: 1) small abortion clinics, 2) large abortion clinics, 3) primary care clinics, 4) low volume hospitals, and 5) high volume hospitals. In ten states we also used publicly available state administrative data to supplement our estimates. We developed separate imputations for virtual clinics that did not submit data to us, using the median number of abortions that were provided by other virtual clinics in the state. For virtual clinics with missing months of data, we calculated the average month-to-month change in virtual clinic abortion volume in the state and imputed values.

We reported the number of abortions by state and by restrictiveness level using three categories: states that banned abortion, states that restricted abortion to before detection of embryonic cardiac activity, also referred to as a “6-week bans” because detection of such activity usually occurs around that point, and states that permitted abortion. These categories were based on the abortion policy in each state on the 15th of each month as reported by the New York Times. For a legal analysis of restrictions that prevent explicitly ban telehealth or implicitly preclude telehealth abortion, we rely on the RHITES map. Monthly state totals were rounded to the nearest 10.

#WeCount was deemed exempt by Advarra IRB. This research was sponsored by the Society of Family Planning.

Limitations

Counts are likely an underrepresentation of all abortions in the US. #WeCount has a comprehensive count of abortions provided by licensed clinicians, with more than 81% of all abortions reported and about 19% imputed. Abortions provided by individual hospitals and private practice clinicians may be underreported. These counts also do not include abortions that take place in the US outside of the formal healthcare system.

#WeCount reports abortion service type by distinguishing telehealth from in-person abortion care. #WeCount does not report medication abortions separately from procedural abortions. Thus, the in-person abortion counts include both medication and procedural abortions that were provided in clinics, while all telehealth abortions are medication abortions.

We do not have estimates of the proportion of people who did not take the medications sent to them. These data show telehealth abortions as the providers documented mailing them. Some people may not have taken the pills, and we do not have an estimate of that. Use of shield laws to provide abortion via telehealth into states with total or 6-week abortion bans or with telehealth abortion restrictions started in July 2023, and #WeCount began to count abortions provided under shield laws at that time. Because of this transition in abortion provision, #WeCount does not have a comparator for previous months.

#WeCount cannot estimate unmet needs for abortion. Research has yet to accurately capture the underlying need for abortion. We don't have any counts of the number of people who needed an abortion and didn't get it.
#WeCount is designed to describe changes in abortion access and provision, rather than to explain why these changes are taking place.

Contributors

#WeCount is made possible by the many abortion providers who generously reported their data in support of this effort. This report was prepared by the #WeCount Co-Chairs and Society of Family Planning staff, as well as many members of the Society of Family Planning community.

#WeCount Co-Chairs

- Alison Norris, MD, PhD; Ohio State University
- Ushma Upadhyay, PhD, MPH; University of California, San Francisco

#WeCount Society of Family Planning staff

- Leah Koenig, PhD, MSPH; #WeCount Director
- Jenny O'Donnell, ScD, MS; Vice President of Research and Evaluation
- Claire Yuan, MPP; #WeCount Data Manager

EXHIBIT 2

#WeCount Report Summary Slides with National and 51 State-Level Findings April 2022 to June 2025 (Dec. 9, 2025)

#WeCount in context: the landscape of research efforts to count abortions

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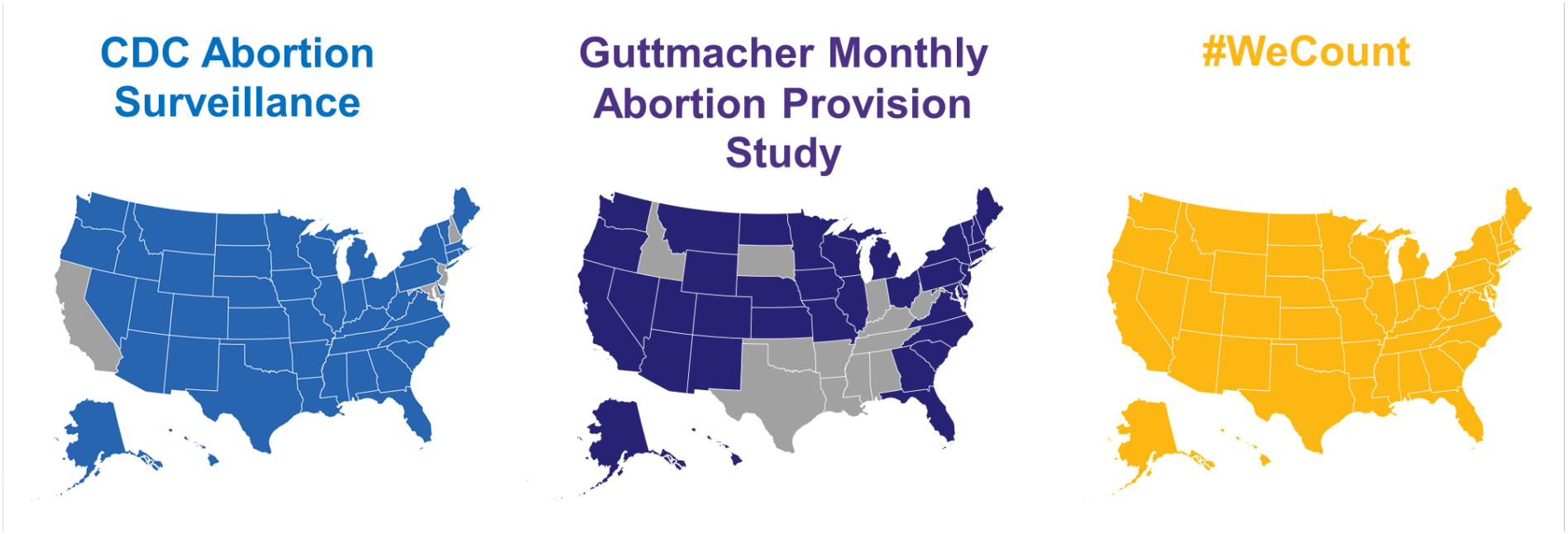
Source: Society of Family Planning, December 2025

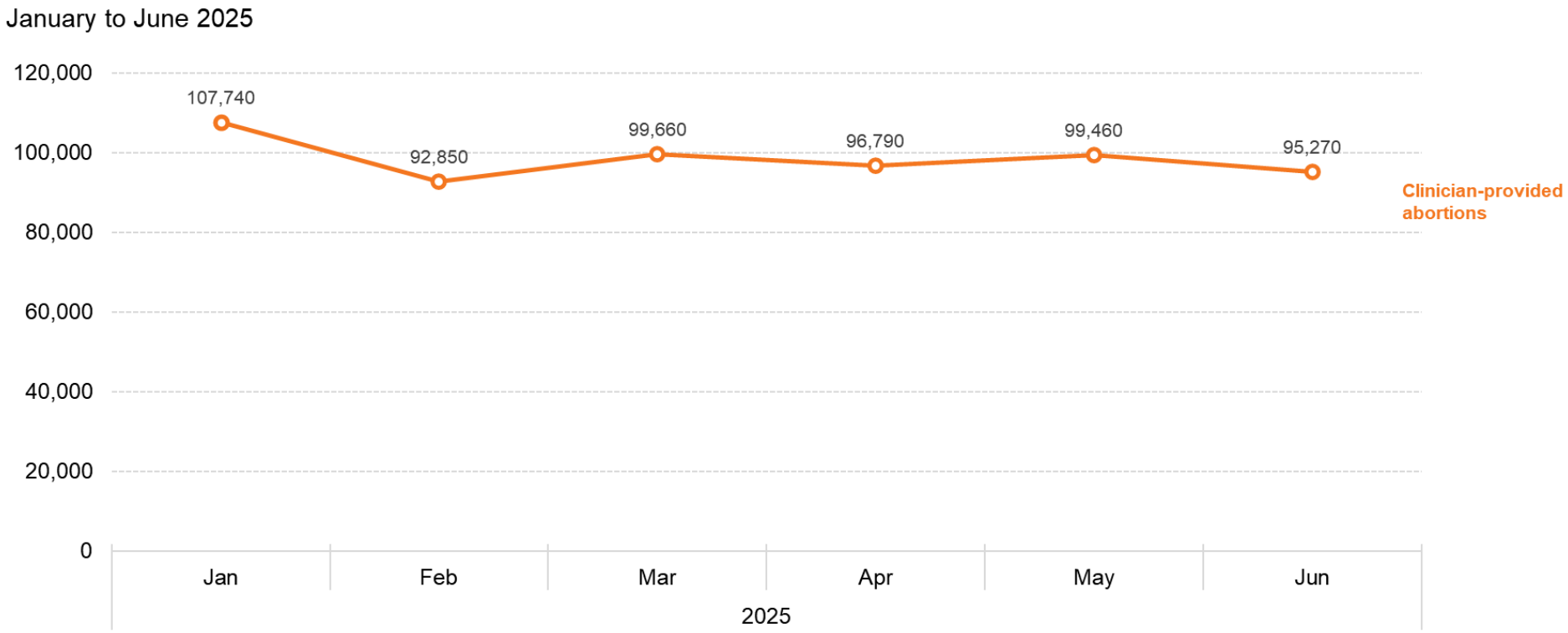
States reflected across efforts to count abortions



Source: Society of Family Planning, December 2025

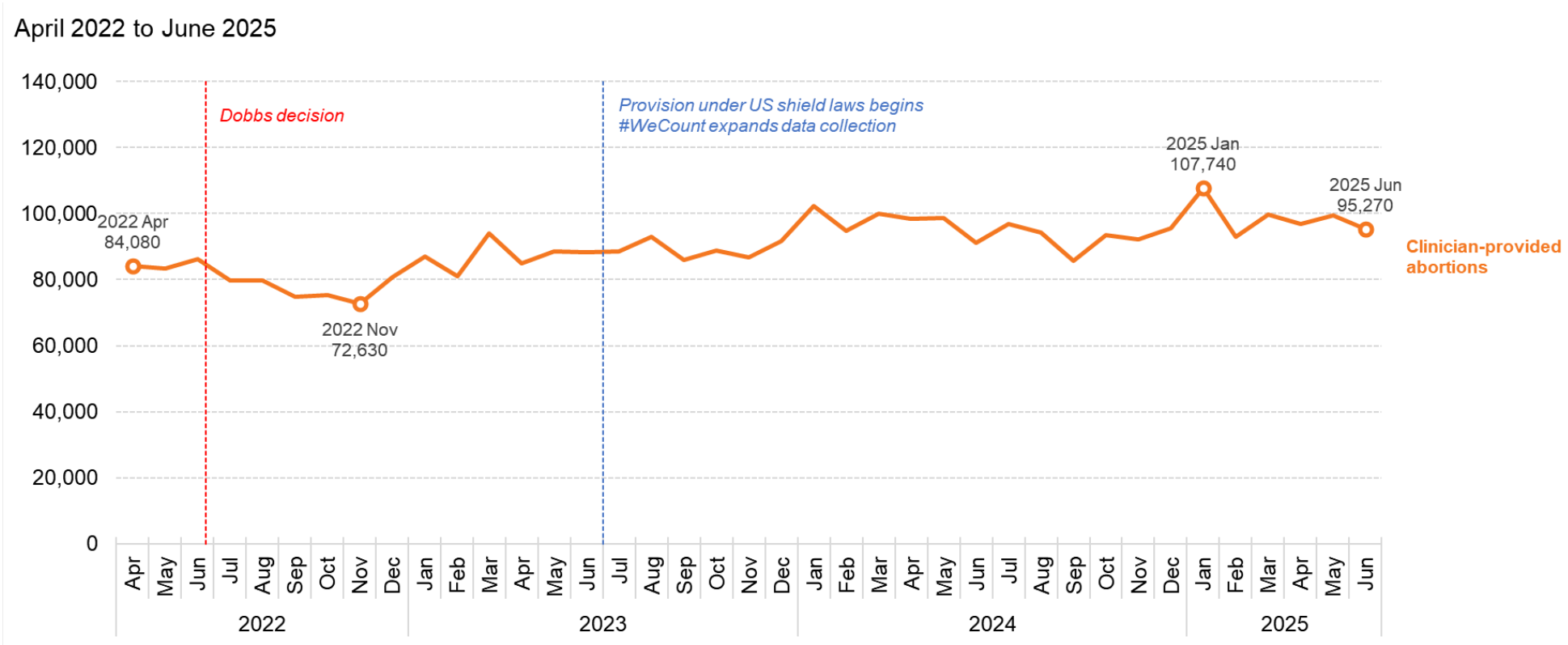
National findings

US abortions totaled 591,770 in the first six months of 2025



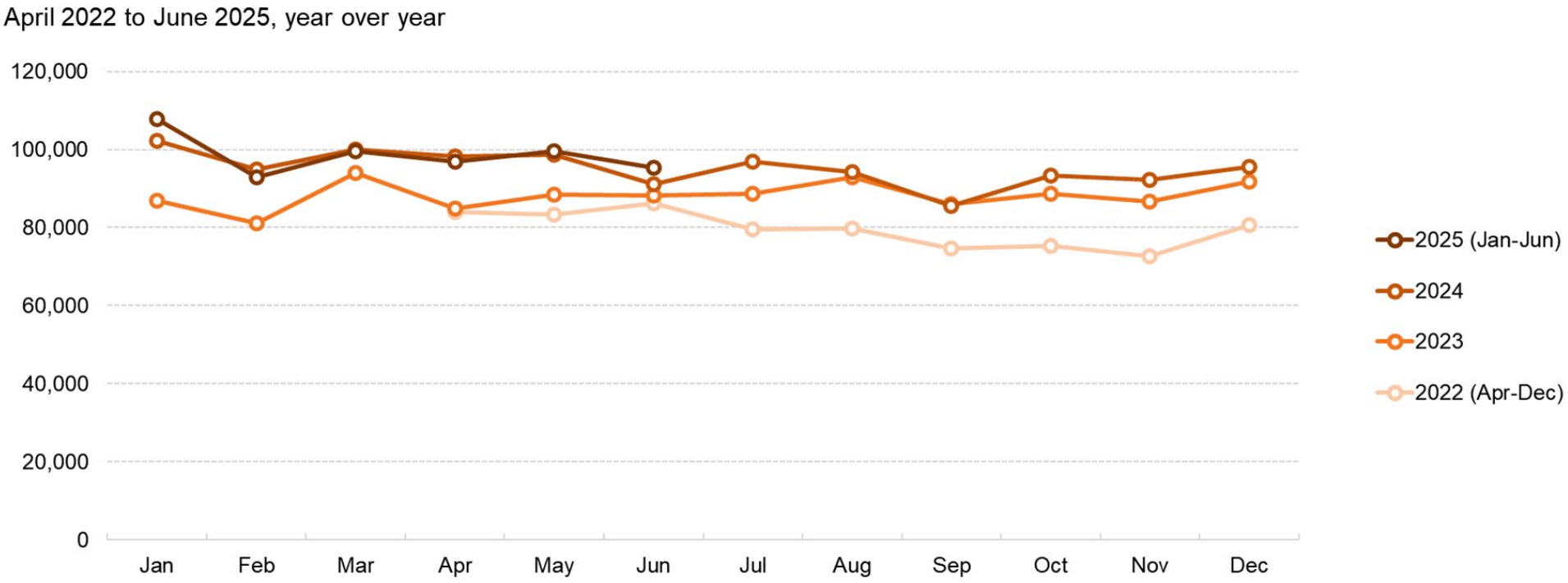
Source: Society of Family Planning, December 2025

Abortions in the US have increased since *Dobbs*



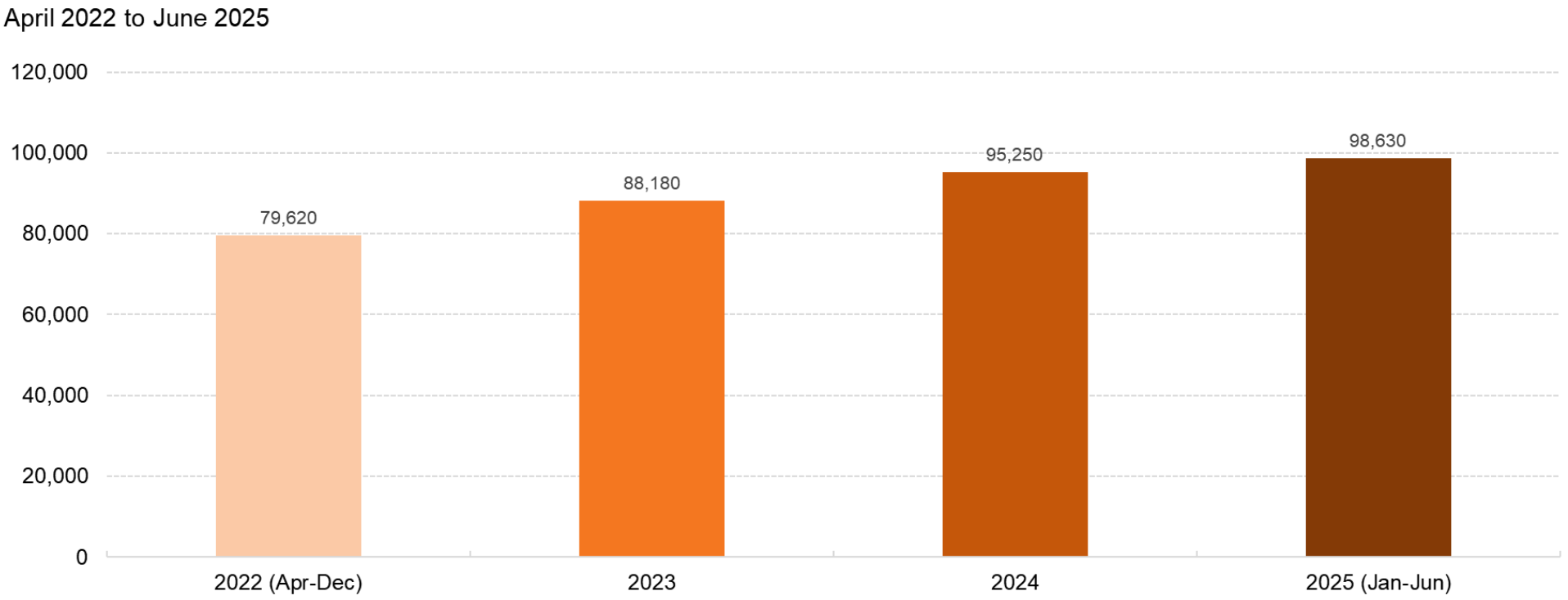
Source: Society of Family Planning, December 2025

Abortion volume fluctuates from month to month, and has increased year-over-year



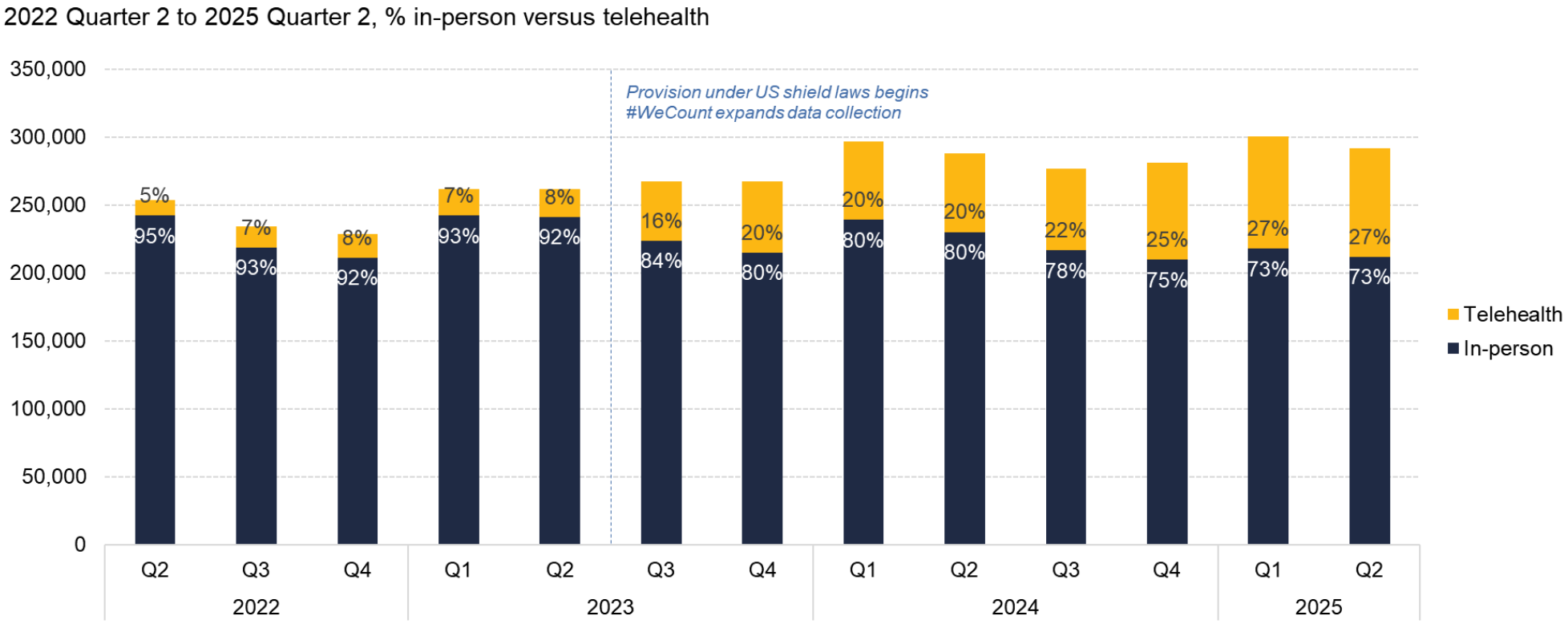
Source: Society of Family Planning, December 2025

Monthly average number of abortions increased each year



Source: Society of Family Planning, December 2025

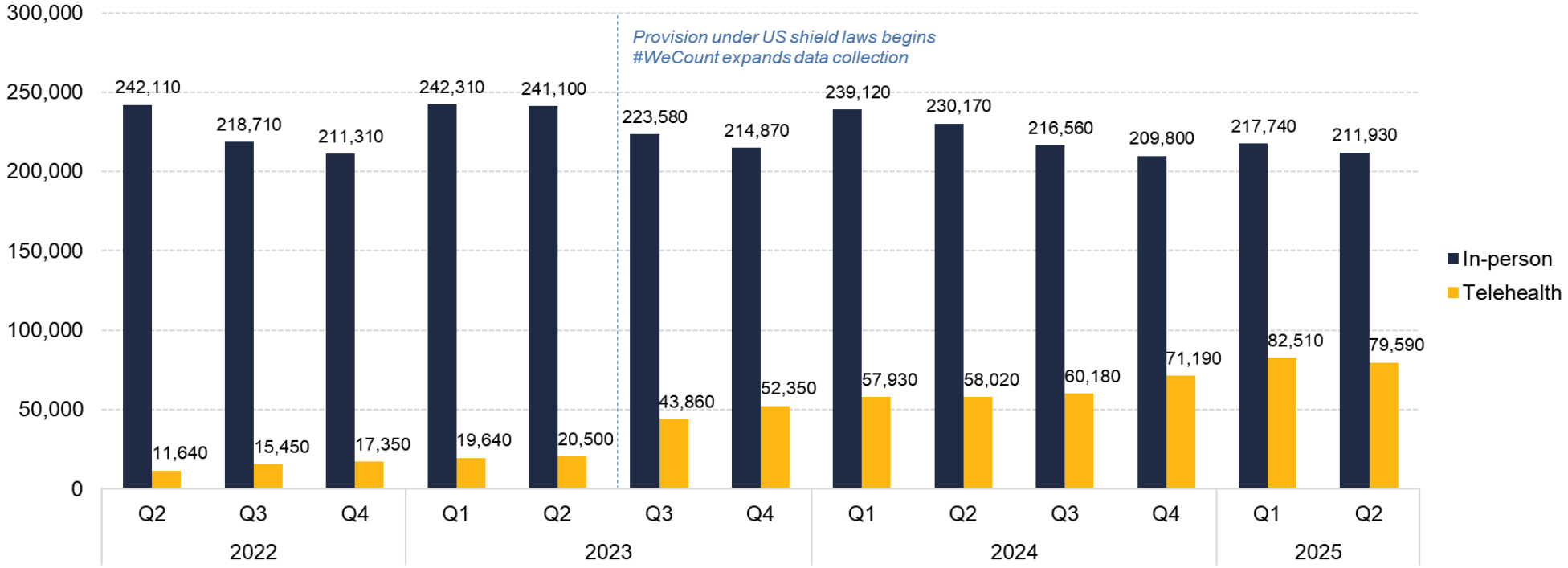
In the first six months of 2025, 27% of abortions were provided via telehealth



Source: Society of Family Planning, December 2025

In-person abortion care declined slightly, while telehealth grew

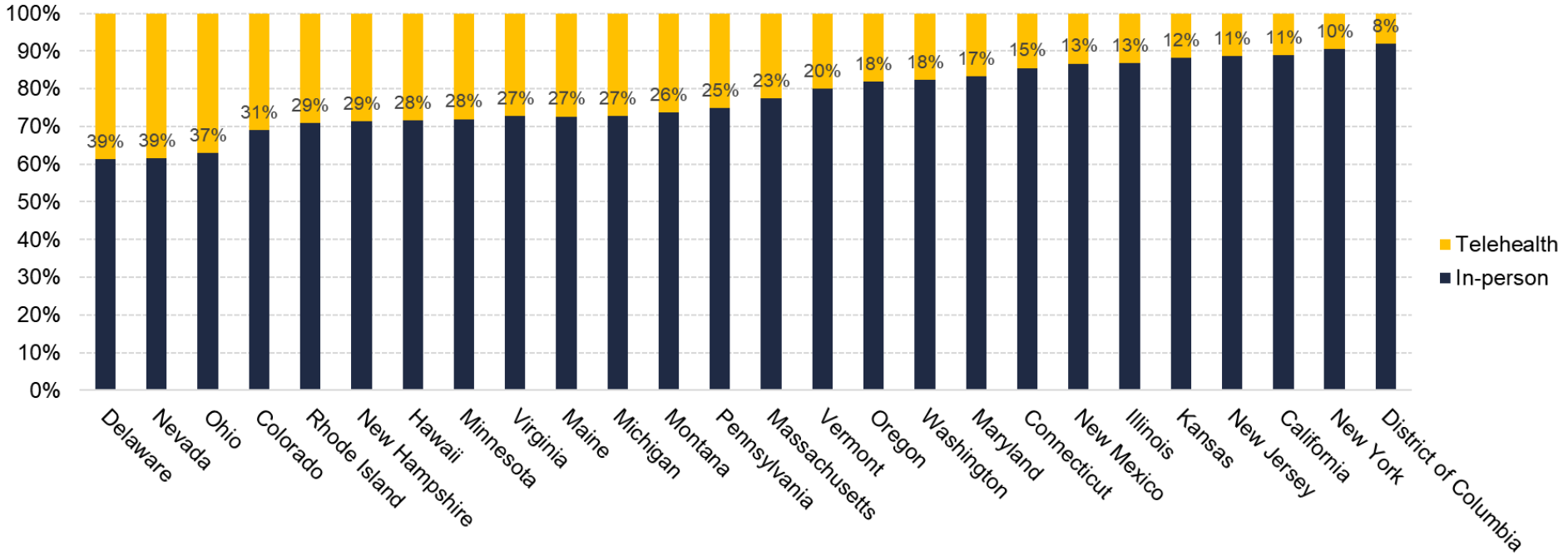
2022 Quarter 2 to 2025 Quarter 2, in-person versus telehealth



Source: Society of Family Planning, December 2025

Where abortion and telehealth are permitted, the share of abortions provided via telehealth varied widely

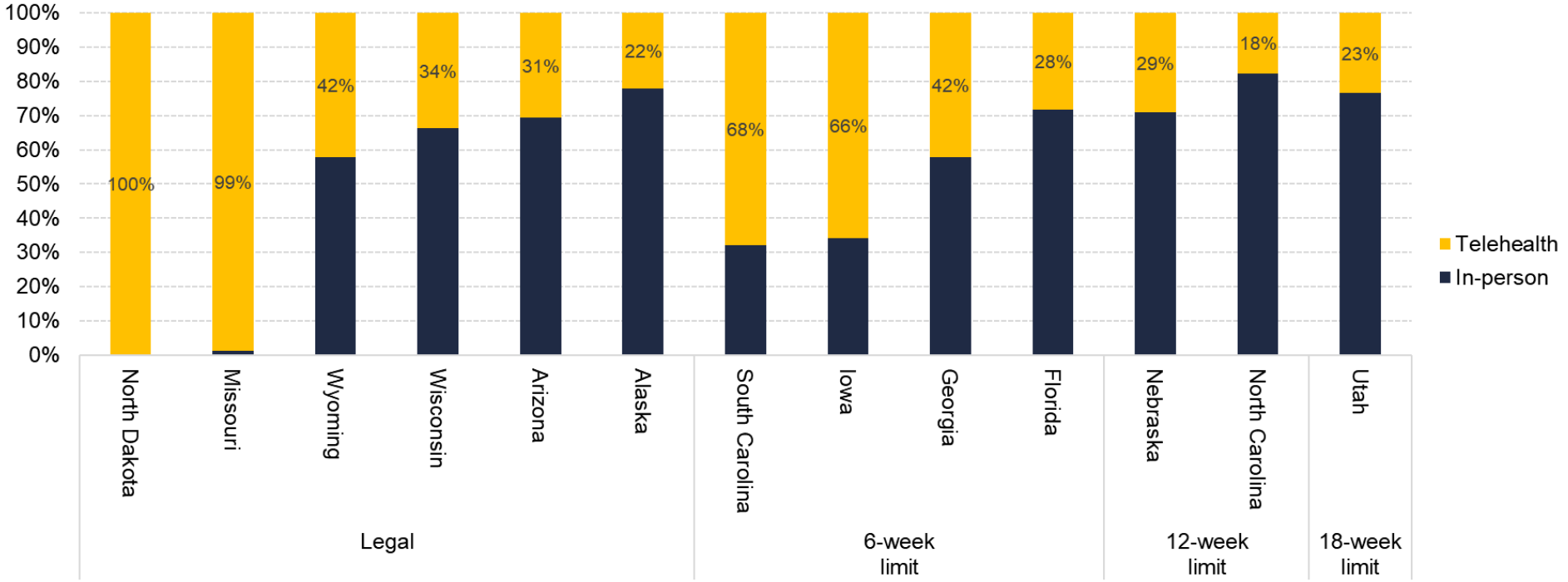
January to June 2025, percent provided via telehealth in states where abortion and telehealth are permitted



Source: Society of Family Planning, December 2025

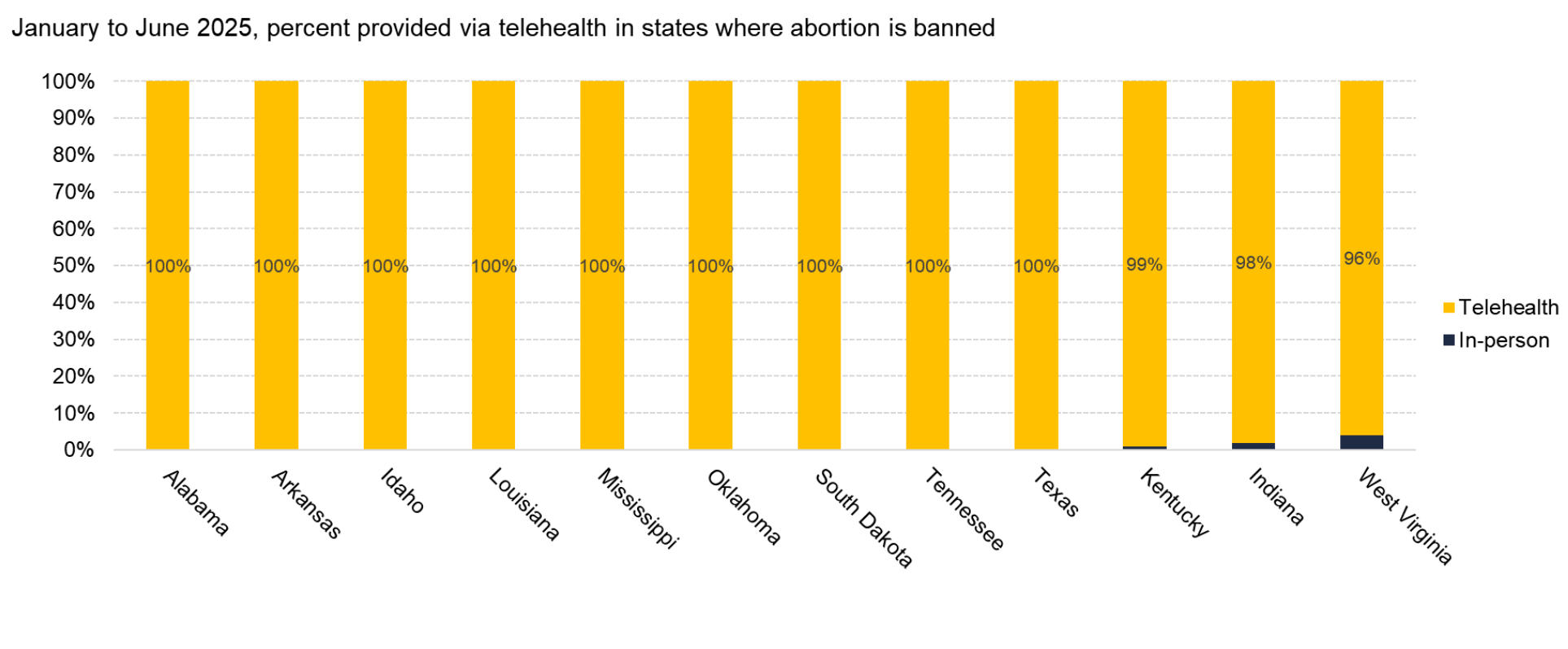
Where telehealth abortion is restricted, the share of abortions provided via telehealth under shield laws varied widely

January to June 2025, percent provided via telehealth in states where telehealth is restricted



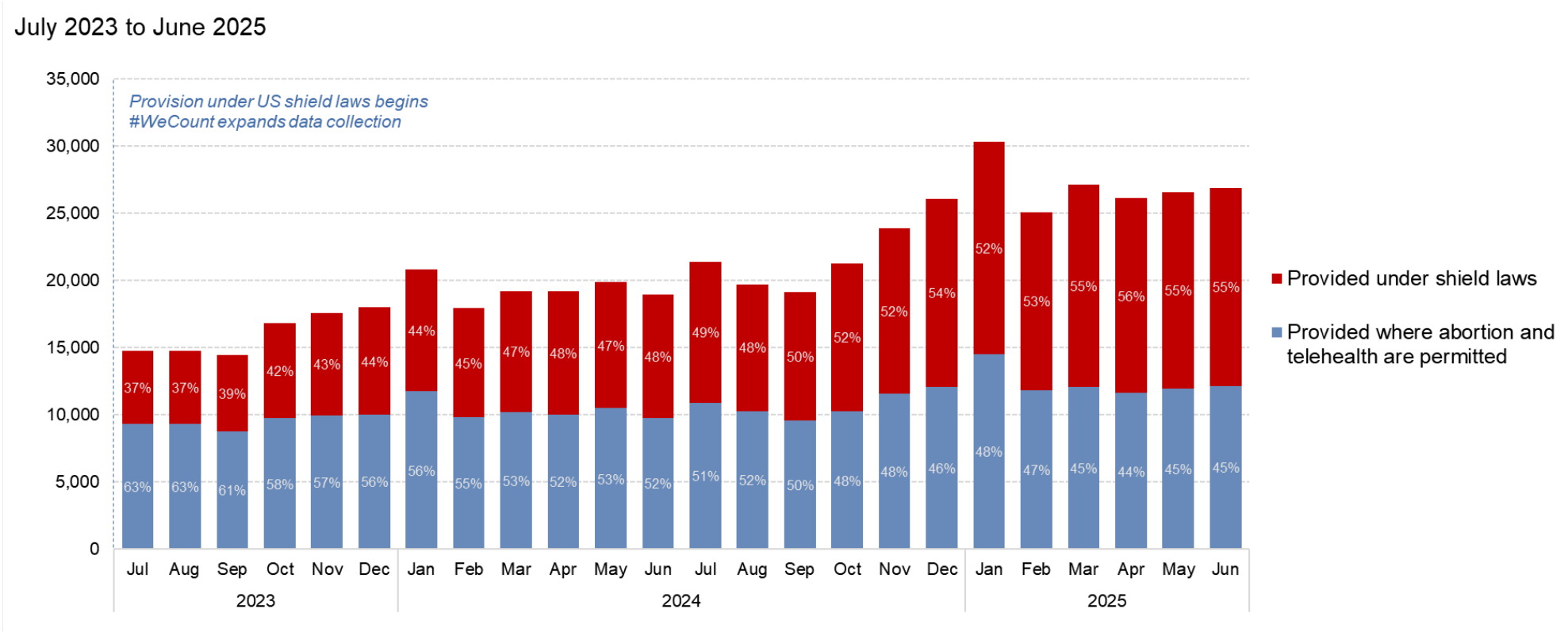
Source: Society of Family Planning, December 2025

Where abortion is banned, nearly all abortions were provided via telehealth under shield laws



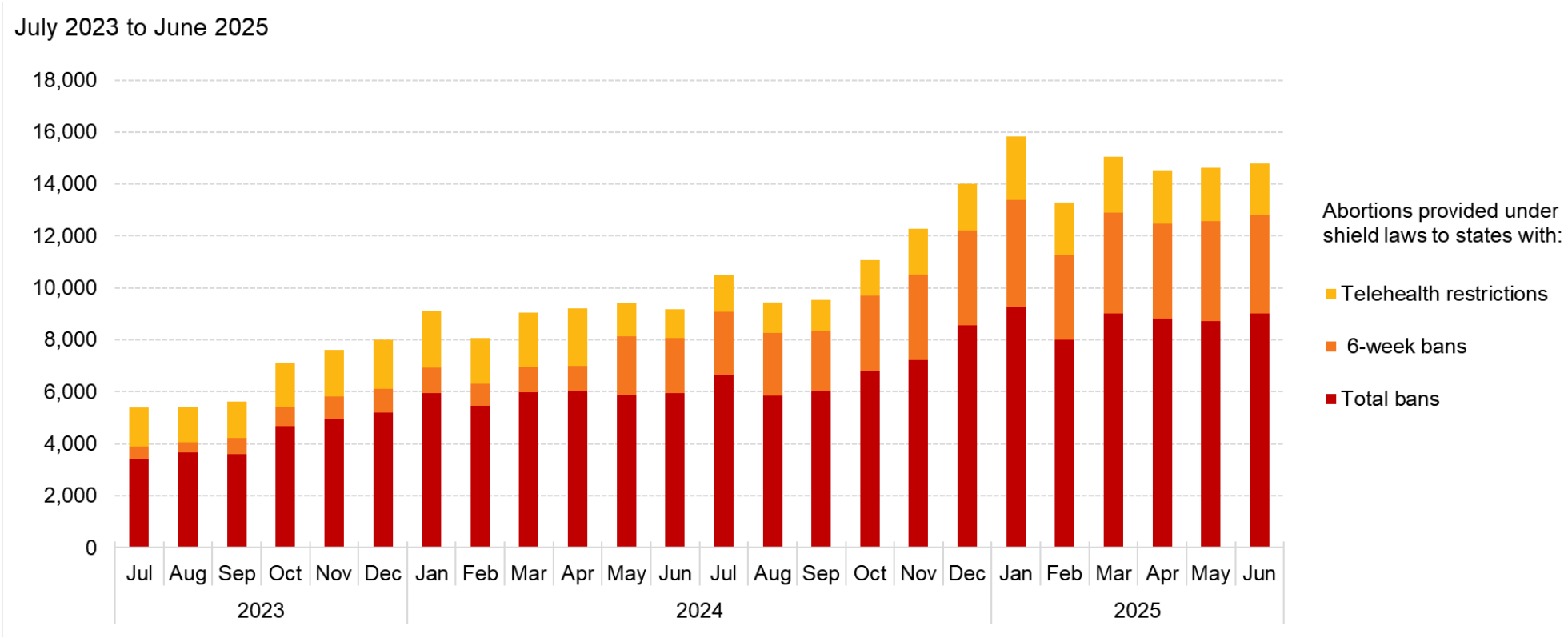
Source: Society of Family Planning, December 2025

A growing share of telehealth abortions are provided under shield laws



Source: Society of Family Planning, December 2025

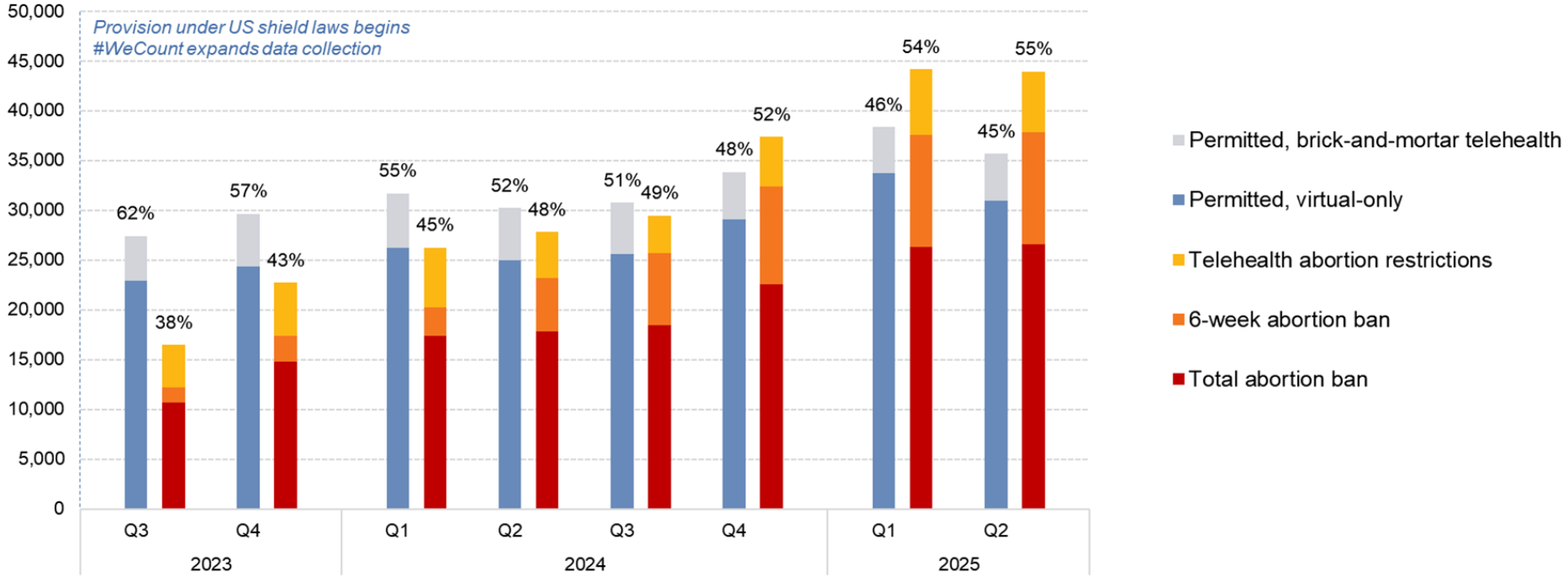
Number of abortions provided via shield laws is increasing



Source: Society of Family Planning, December 2025

Abortions provided under shield laws account for a growing share of all telehealth abortions

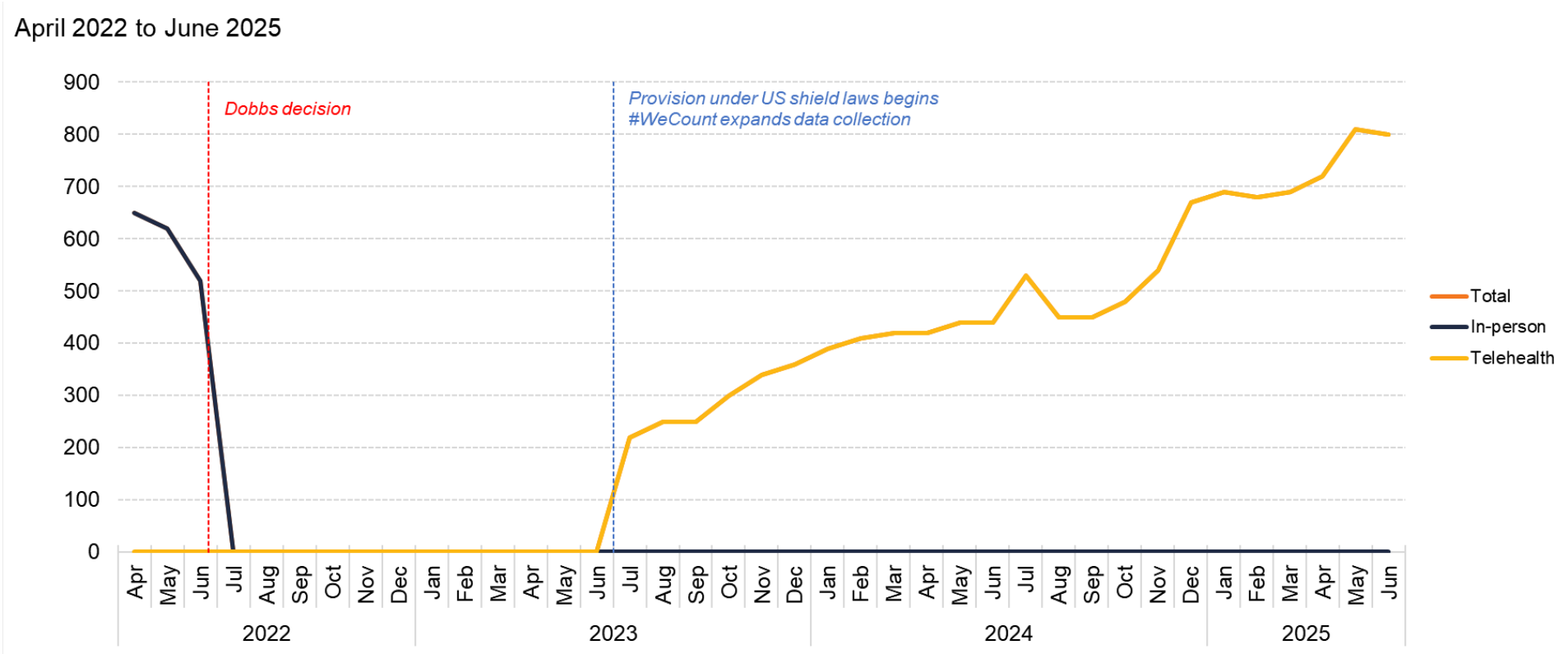
2023 Quarter 3 to 2025 Quarter 2



Source: Society of Family Planning, December 2025

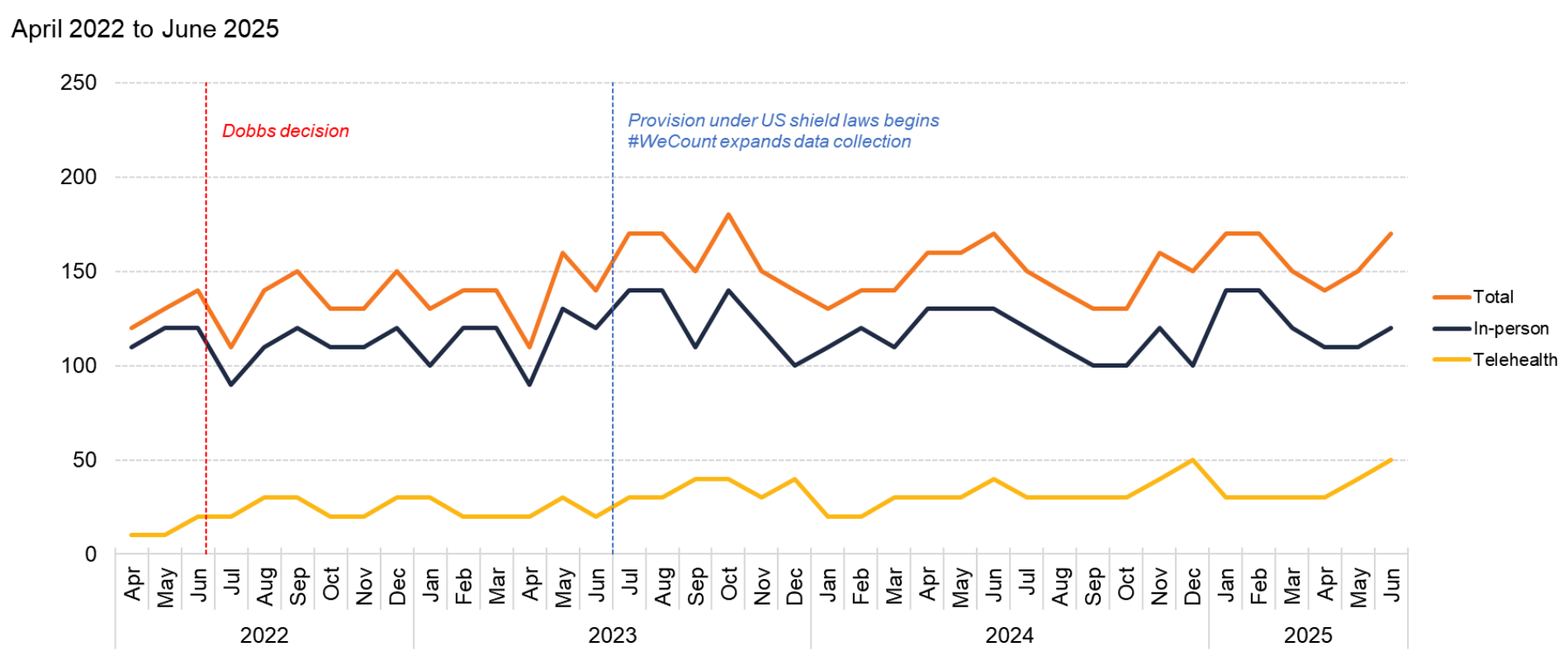
State-level findings

Alabama



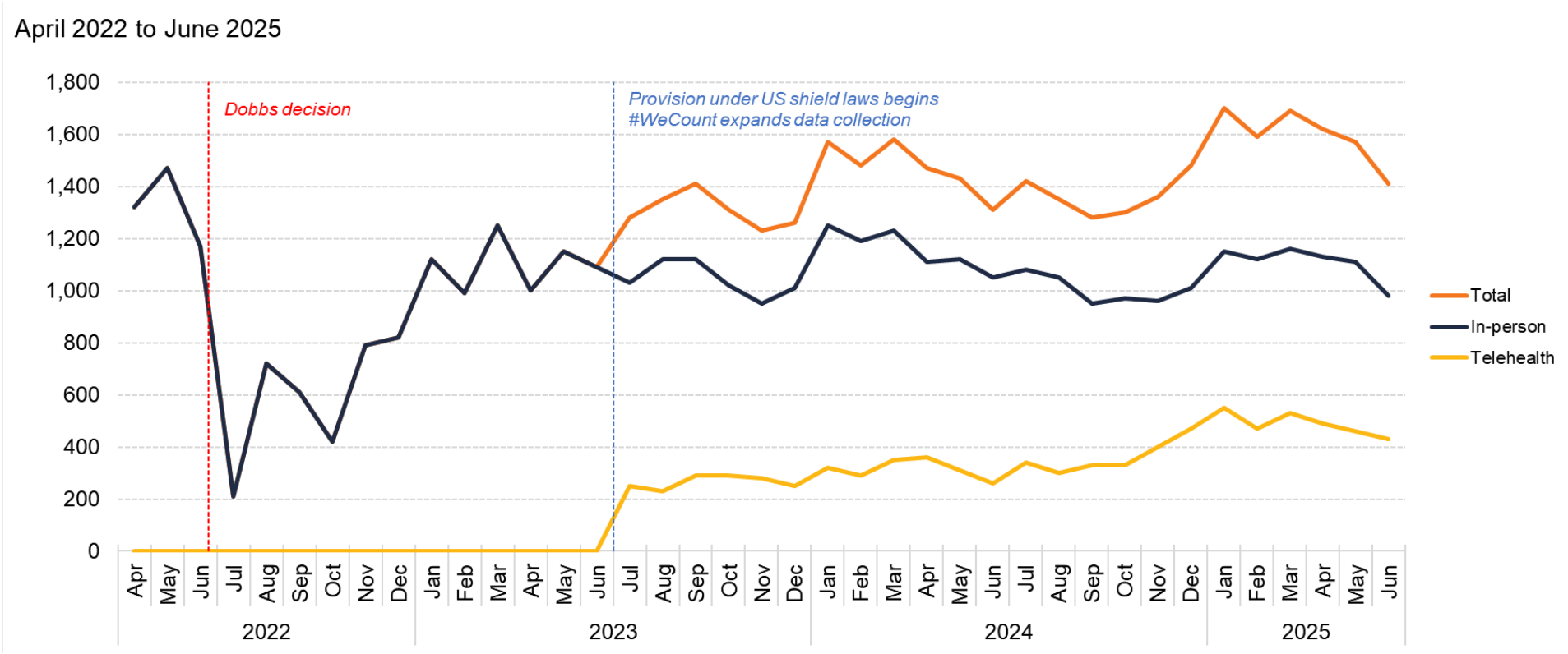
Source: Society of Family Planning, December 2025

Alaska



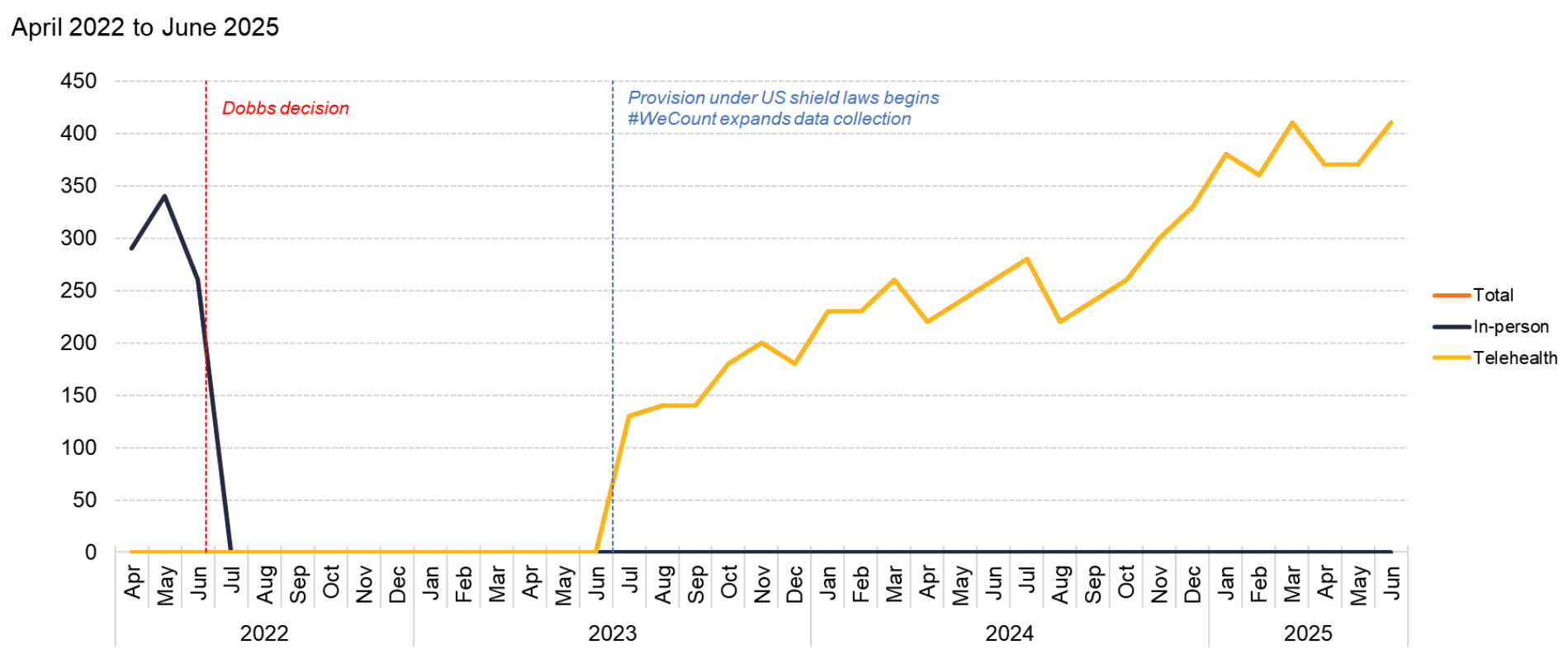
Source: Society of Family Planning, December 2025

Arizona



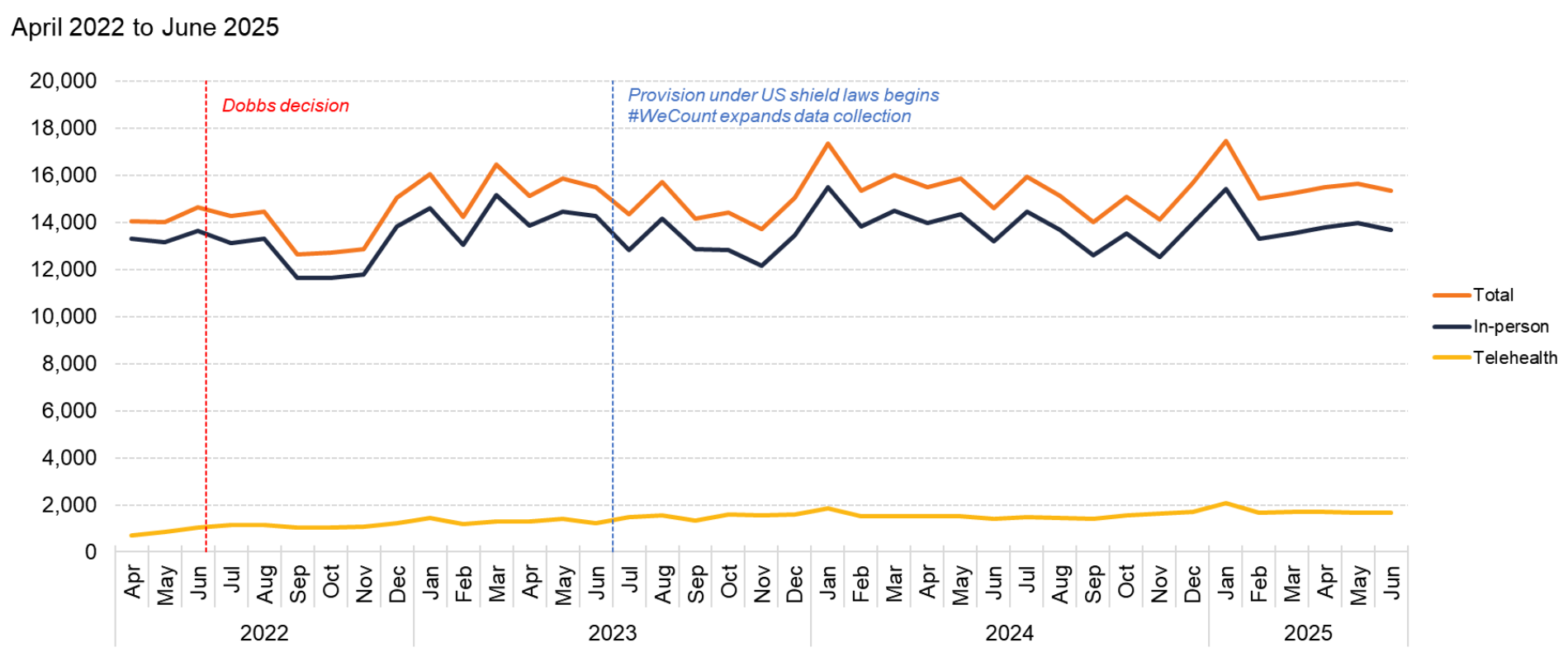
Source: Society of Family Planning, December 2025

Arkansas



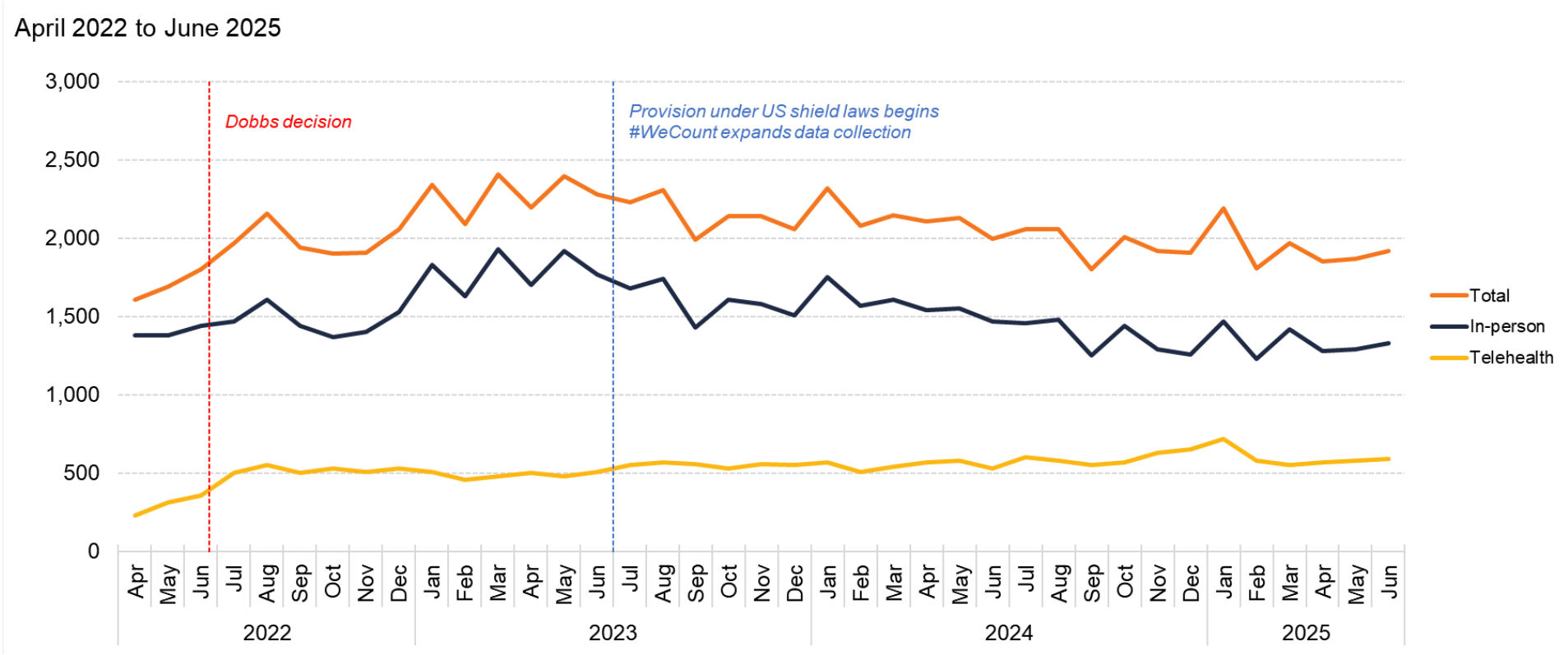
Source: Society of Family Planning, December 2025

California



Source: Society of Family Planning, December 2025

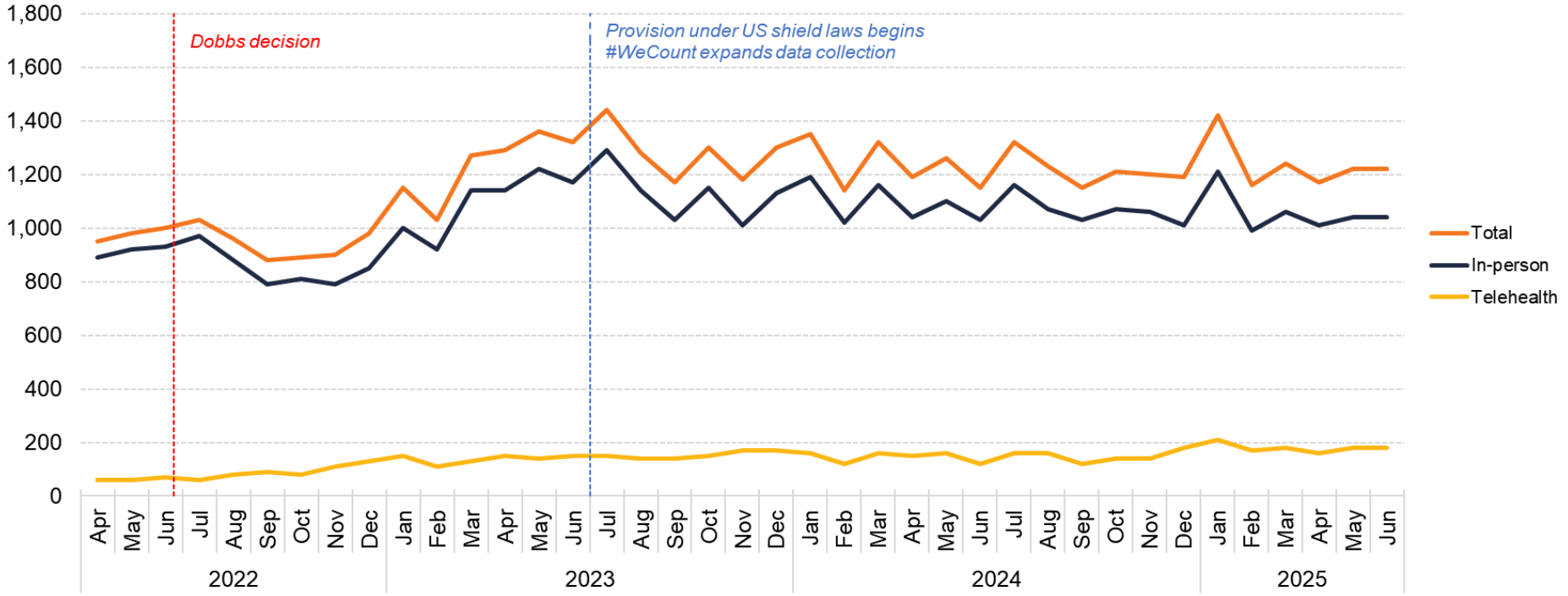
Colorado



Source: Society of Family Planning, December 2025

Connecticut

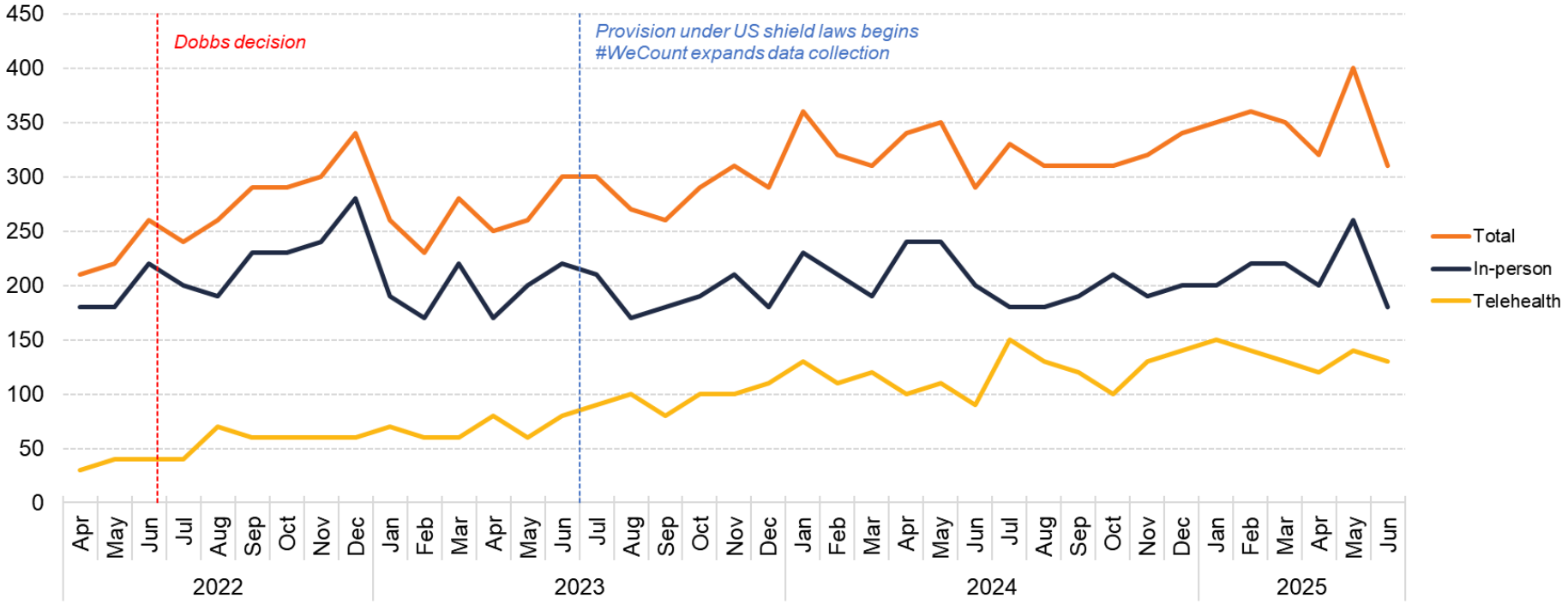
April 2022 to June 2025



Source: Society of Family Planning, December 2025

Delaware

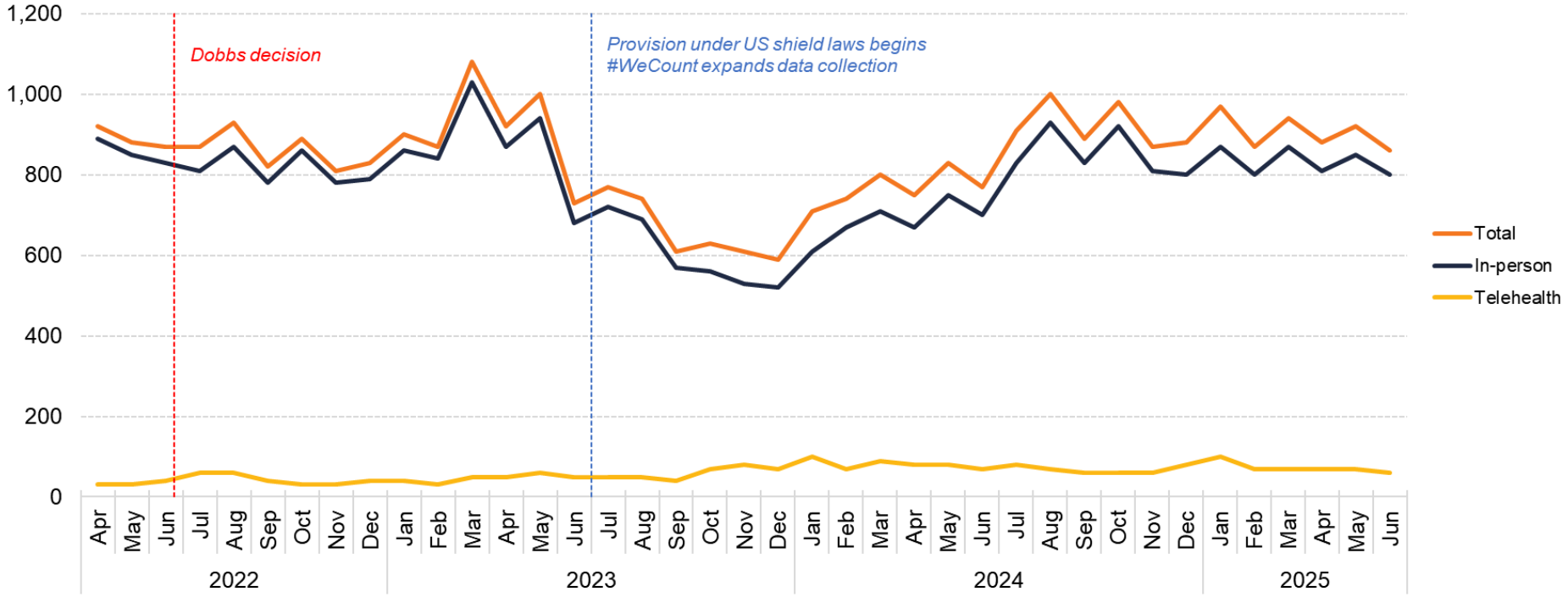
April 2022 to June 2025



Source: Society of Family Planning, December 2025

District of Columbia

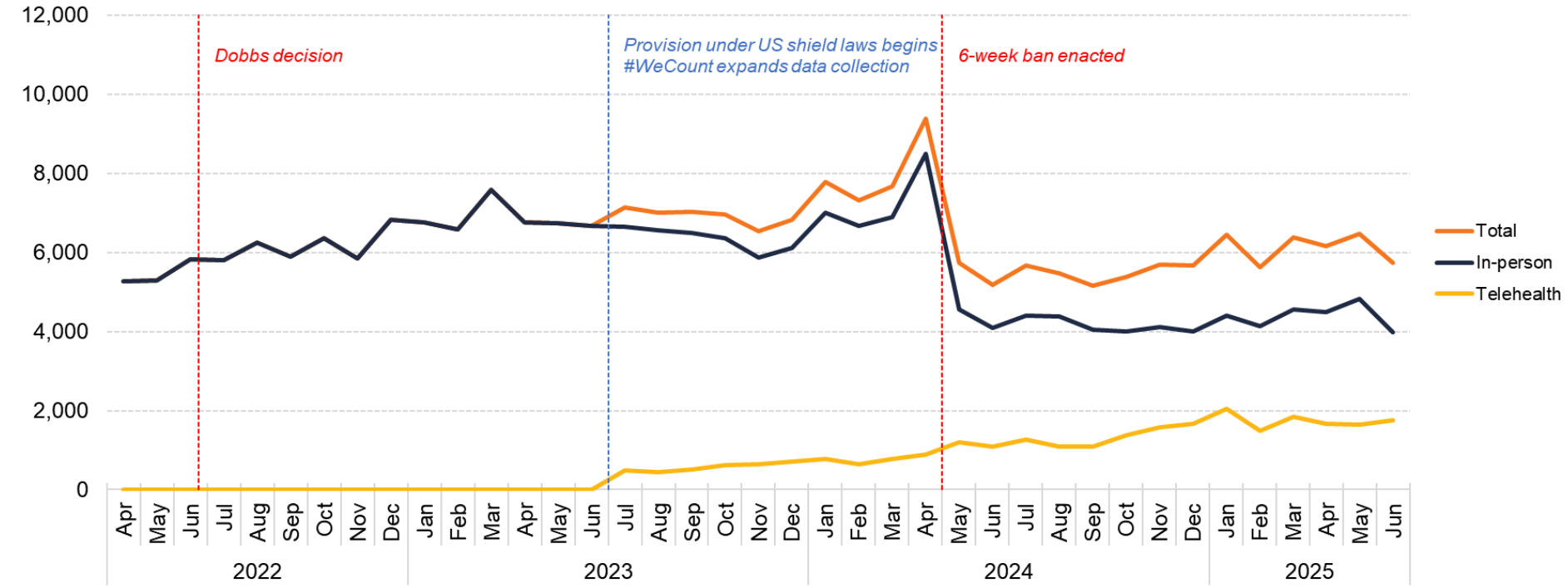
April 2022 to June 2025



Source: Society of Family Planning, December 2025

Florida

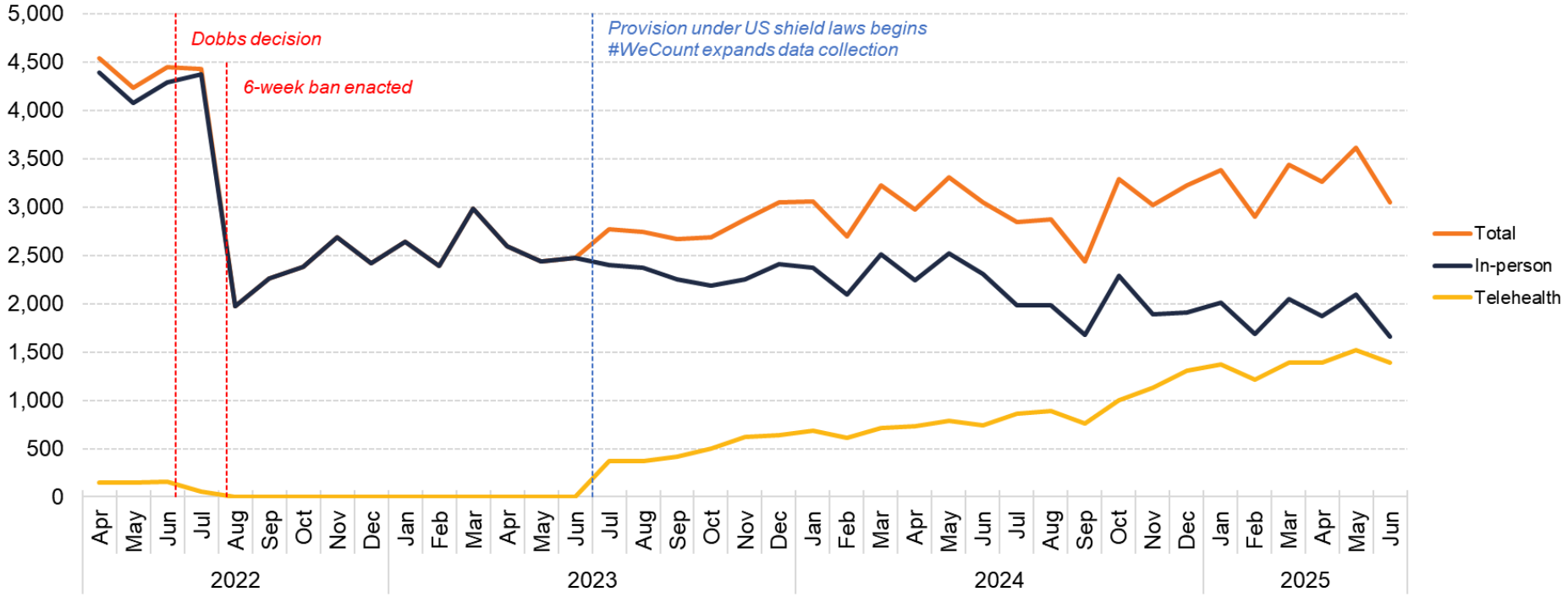
April 2022 to June 2025



Source: Society of Family Planning, December 2025

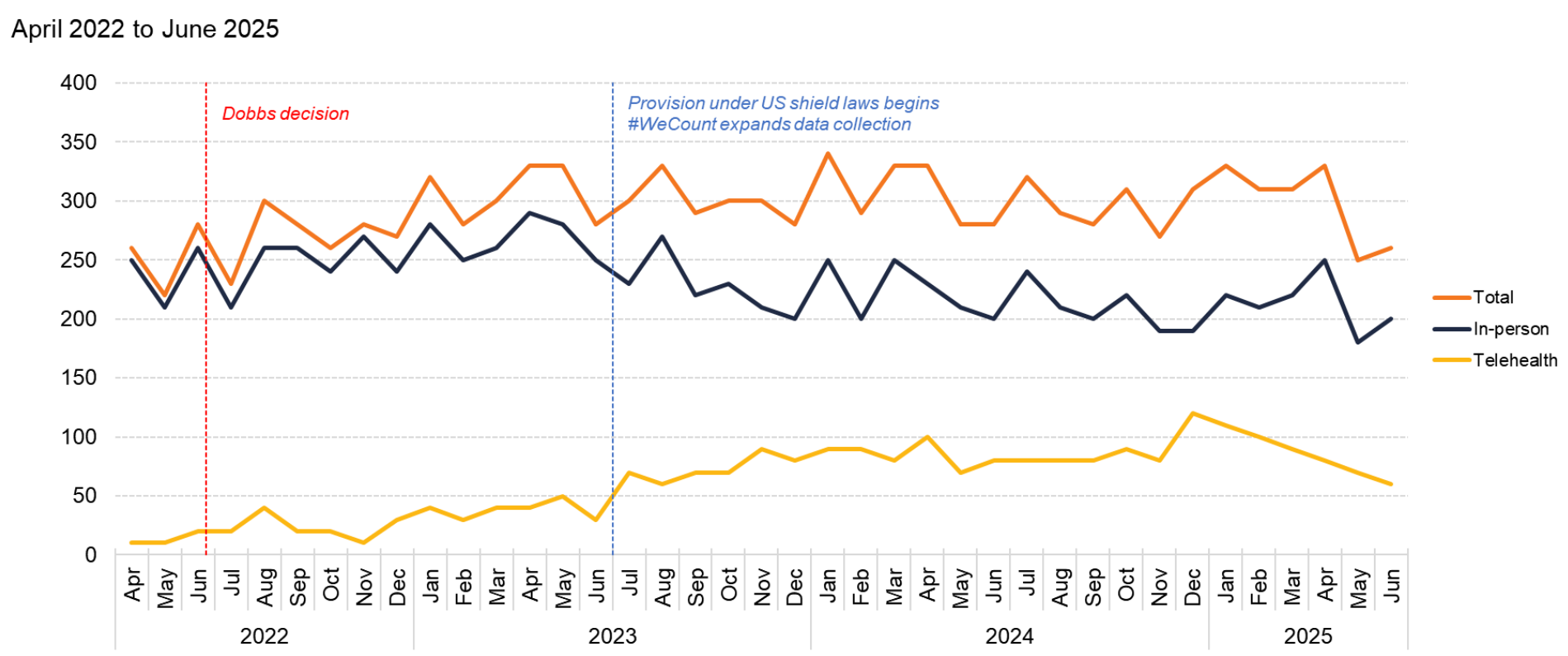
Georgia

April 2022 to June 2025



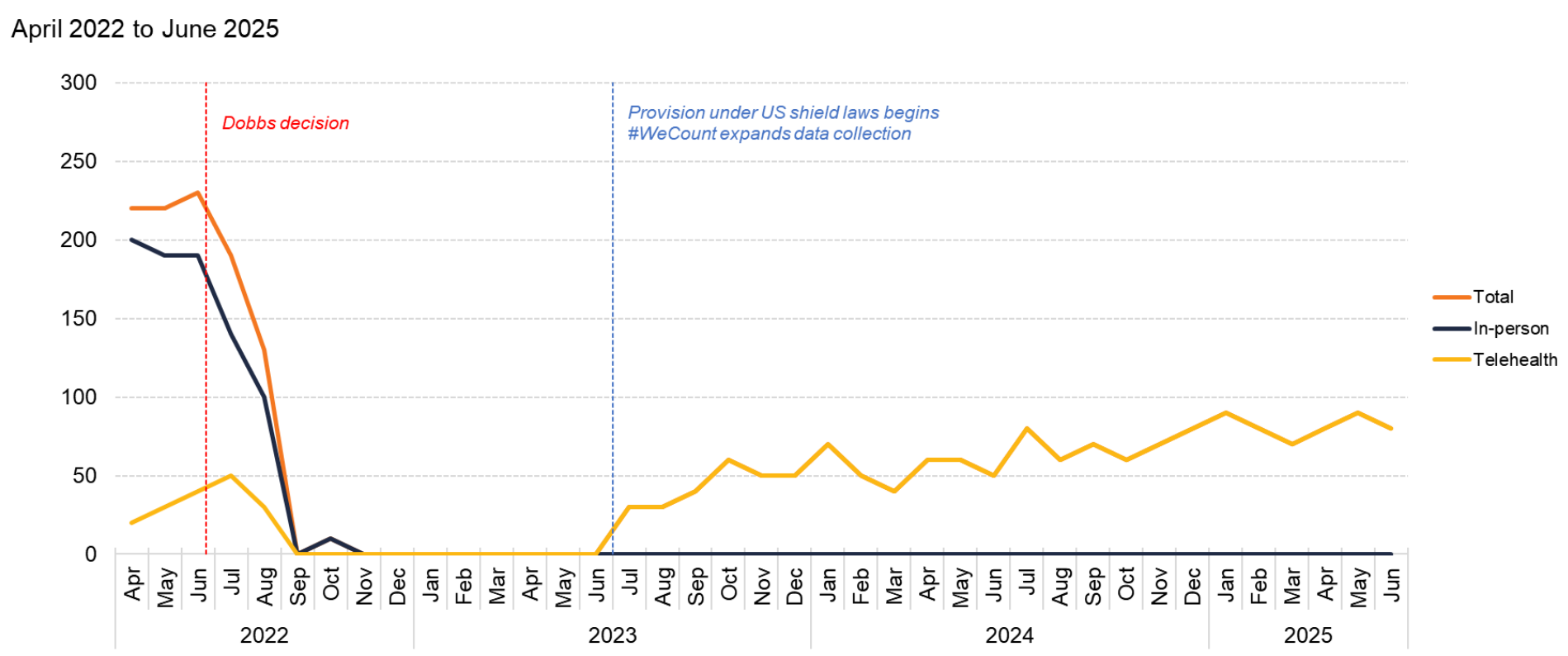
Source: Society of Family Planning, December 2025

Hawaii



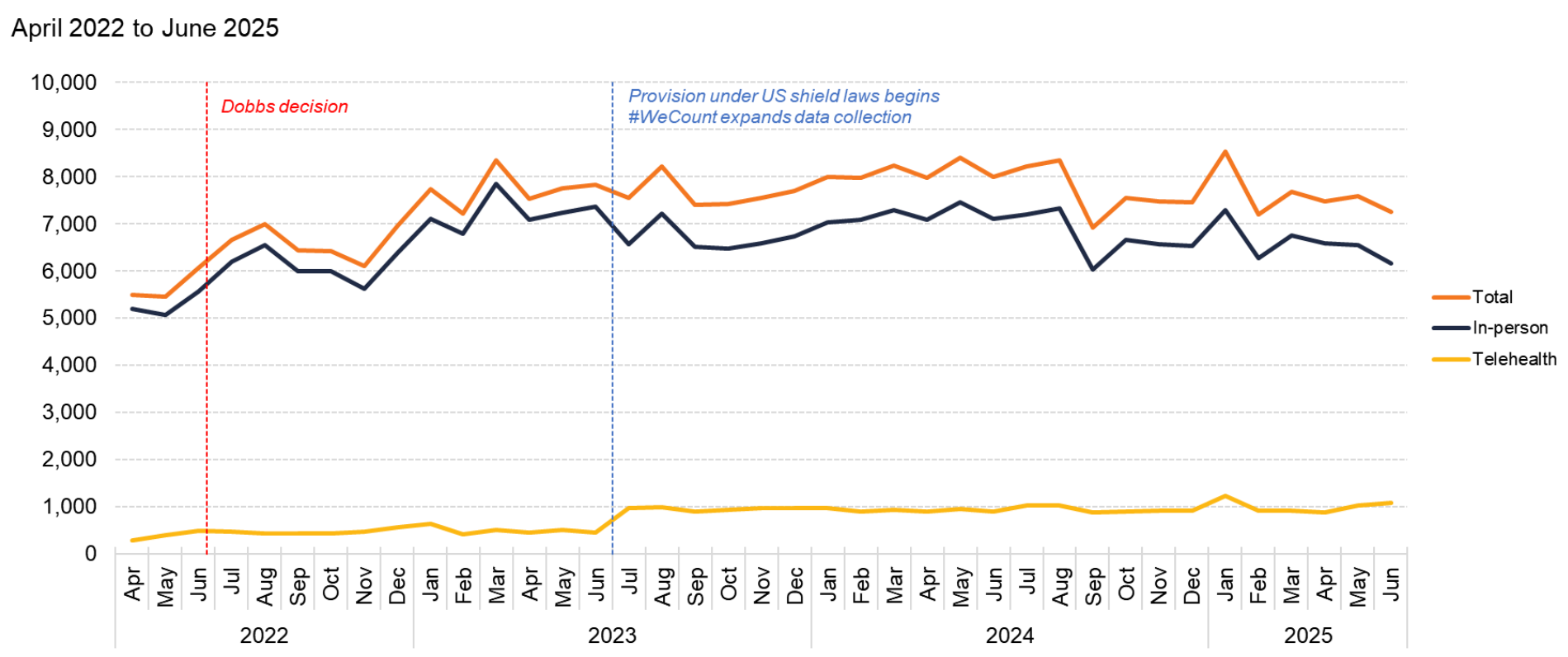
Source: Society of Family Planning, December 2025

Idaho



Source: Society of Family Planning, December 2025

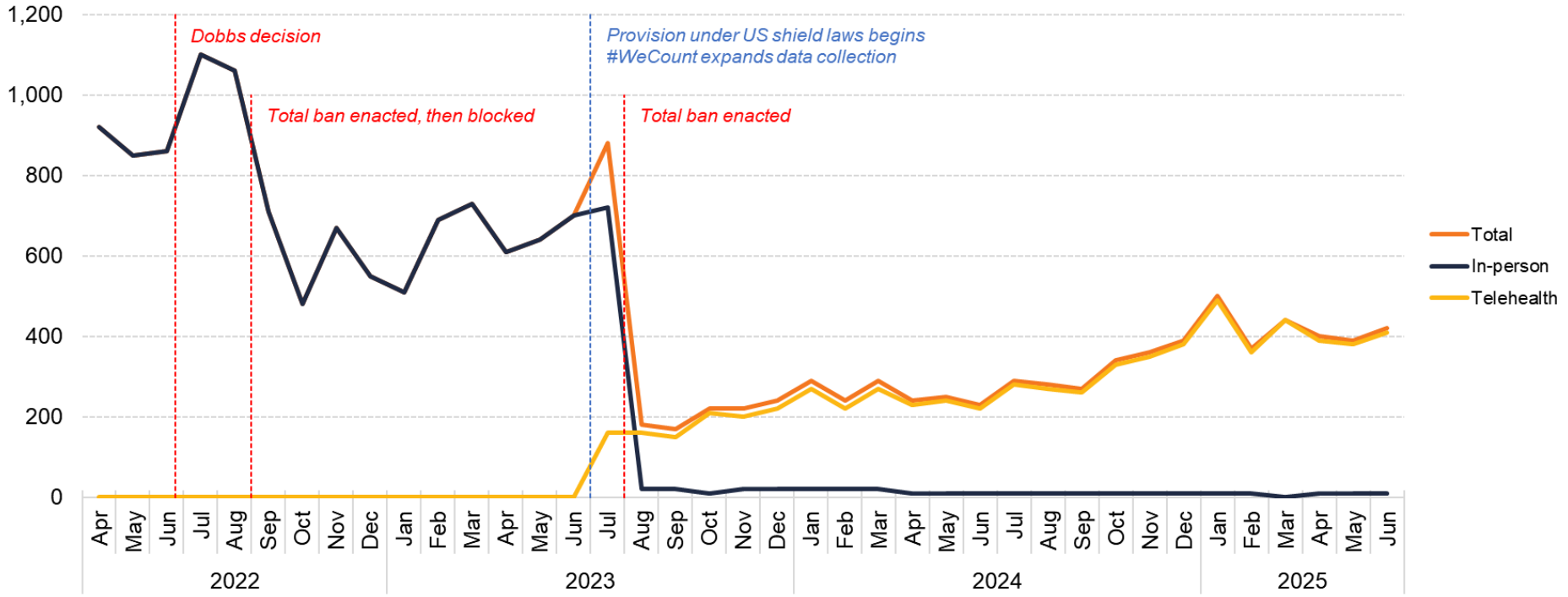
Illinois



Source: Society of Family Planning, December 2025

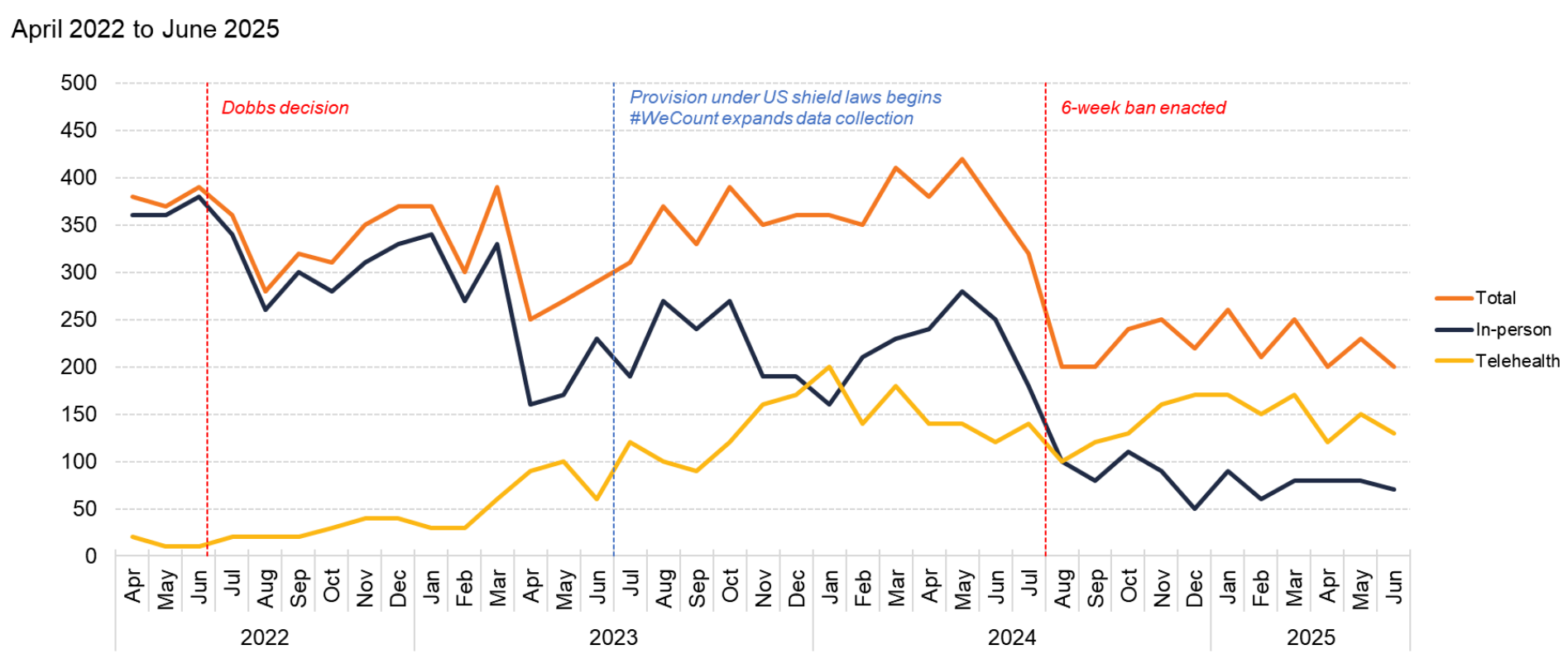
Indiana

April 2022 to June 2025



Source: Society of Family Planning, December 2025

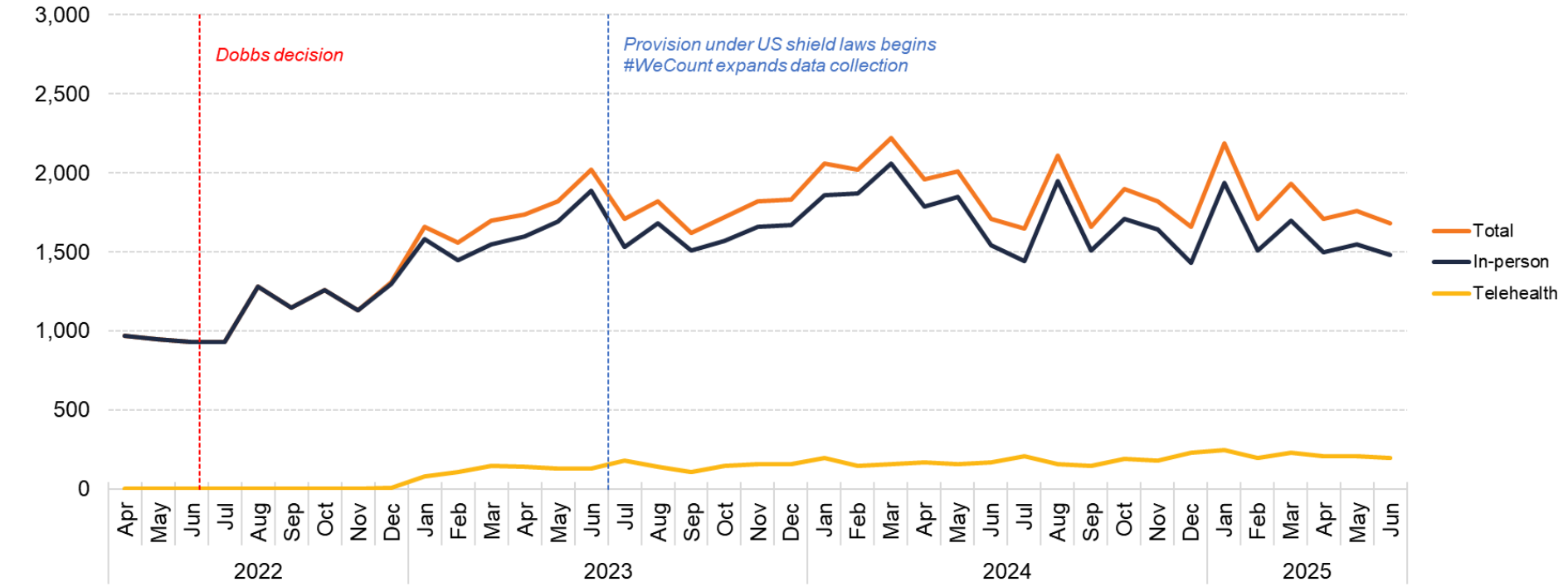
Iowa



Source: Society of Family Planning, December 2025

Kansas

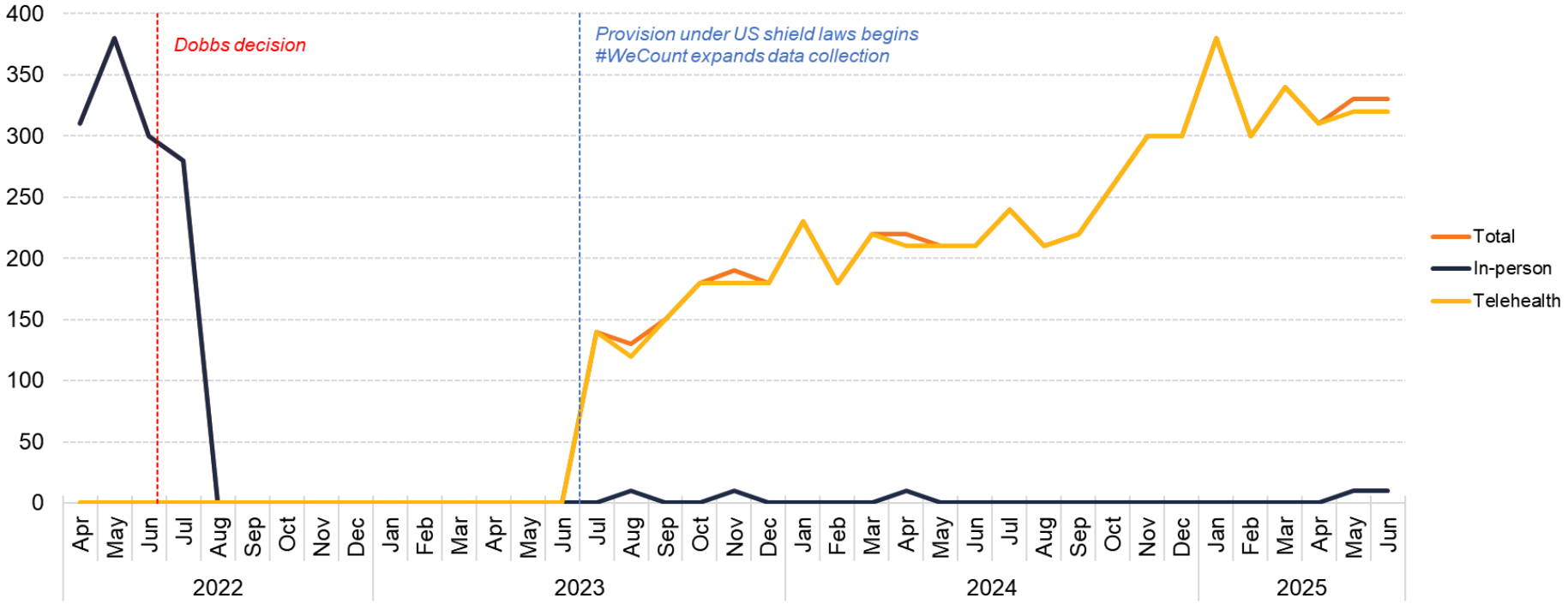
April 2022 to June 2025



Source: Society of Family Planning, December 2025

Kentucky

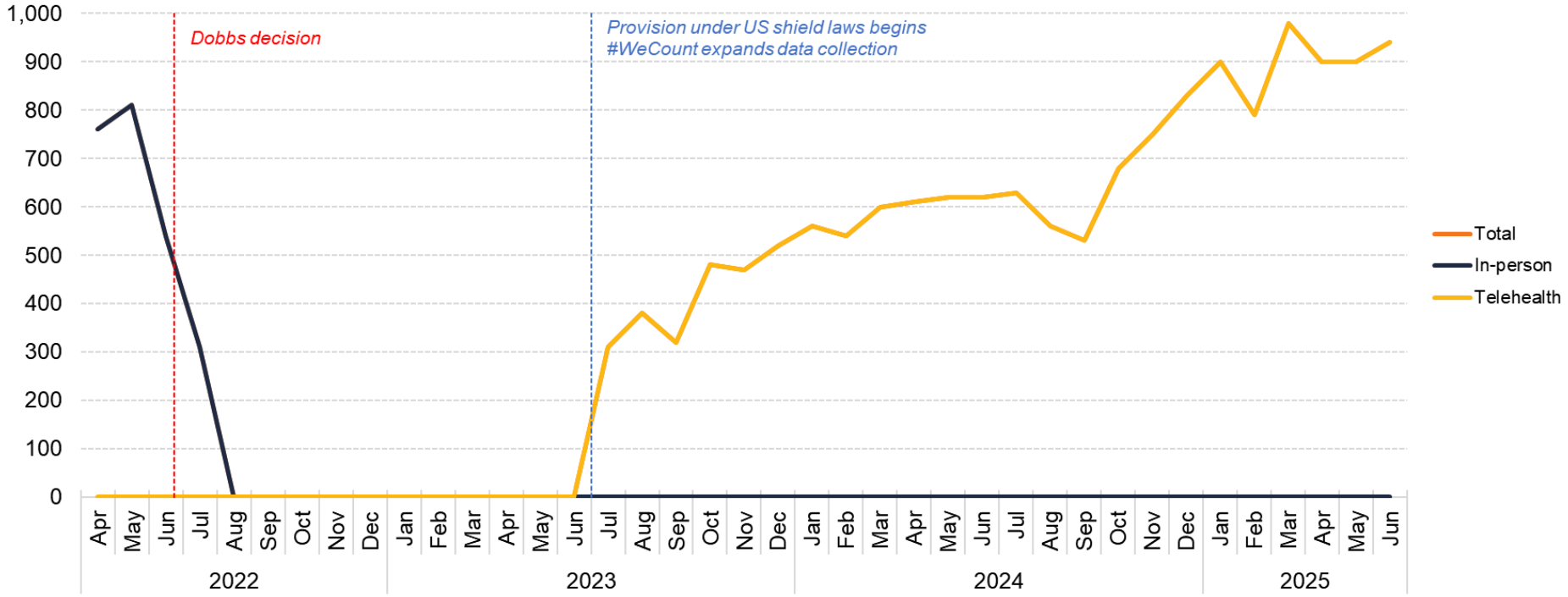
April 2022 to June 2025



Source: Society of Family Planning, December 2025

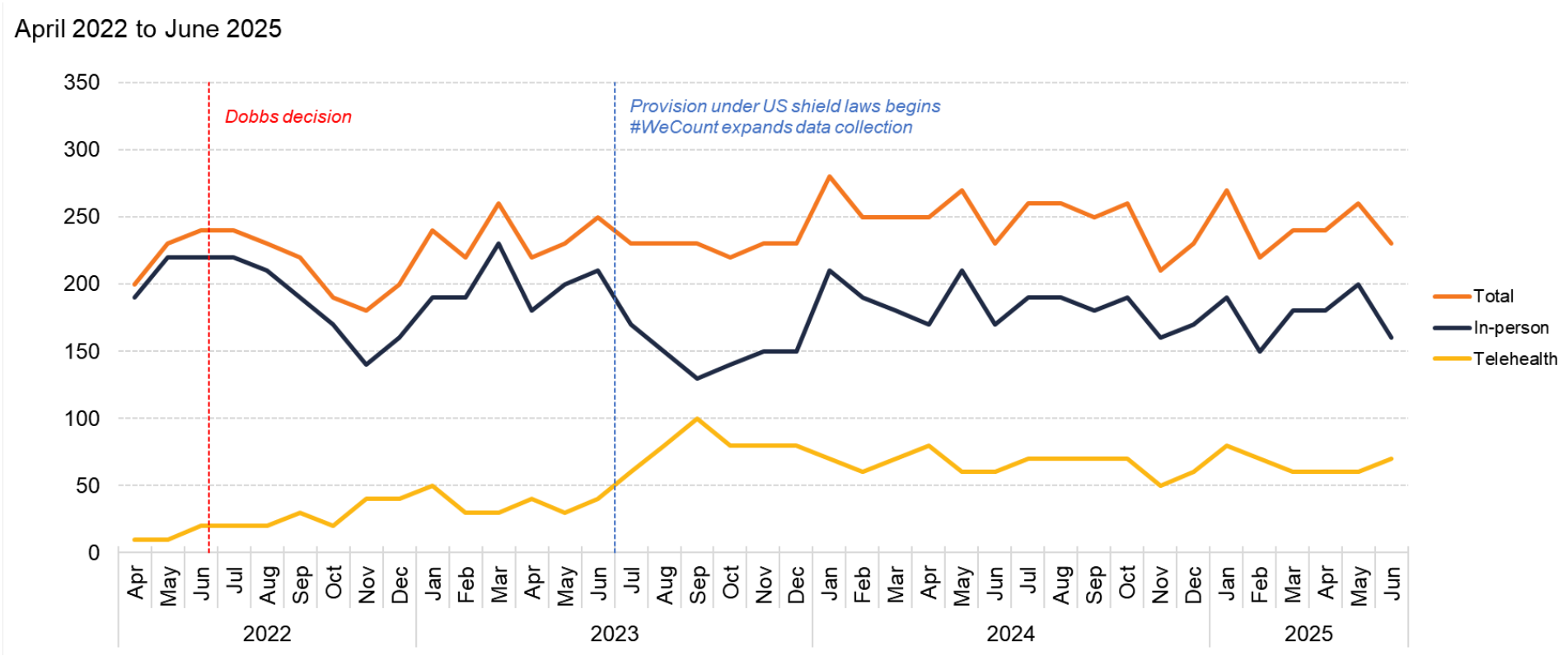
Louisiana

April 2022 to June 2025



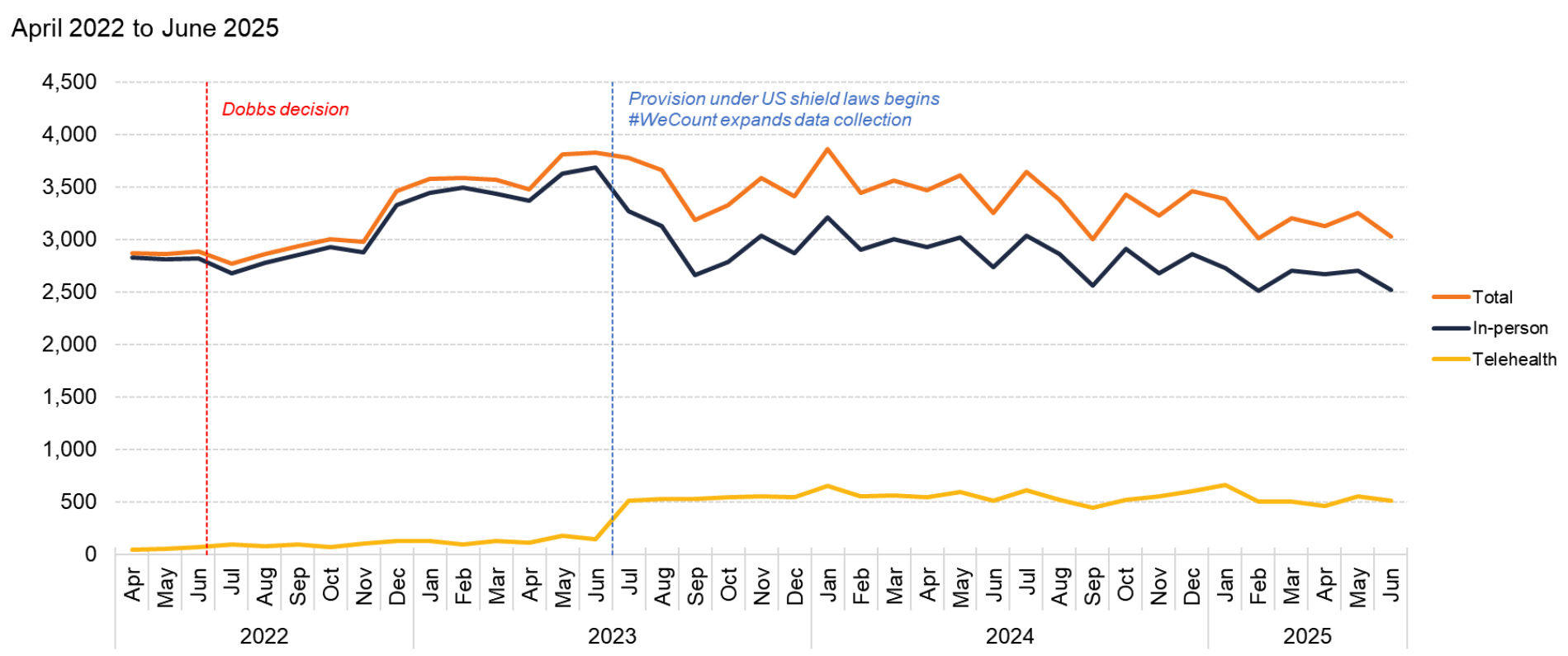
Source: Society of Family Planning, December 2025

Maine



Source: Society of Family Planning, December 2025

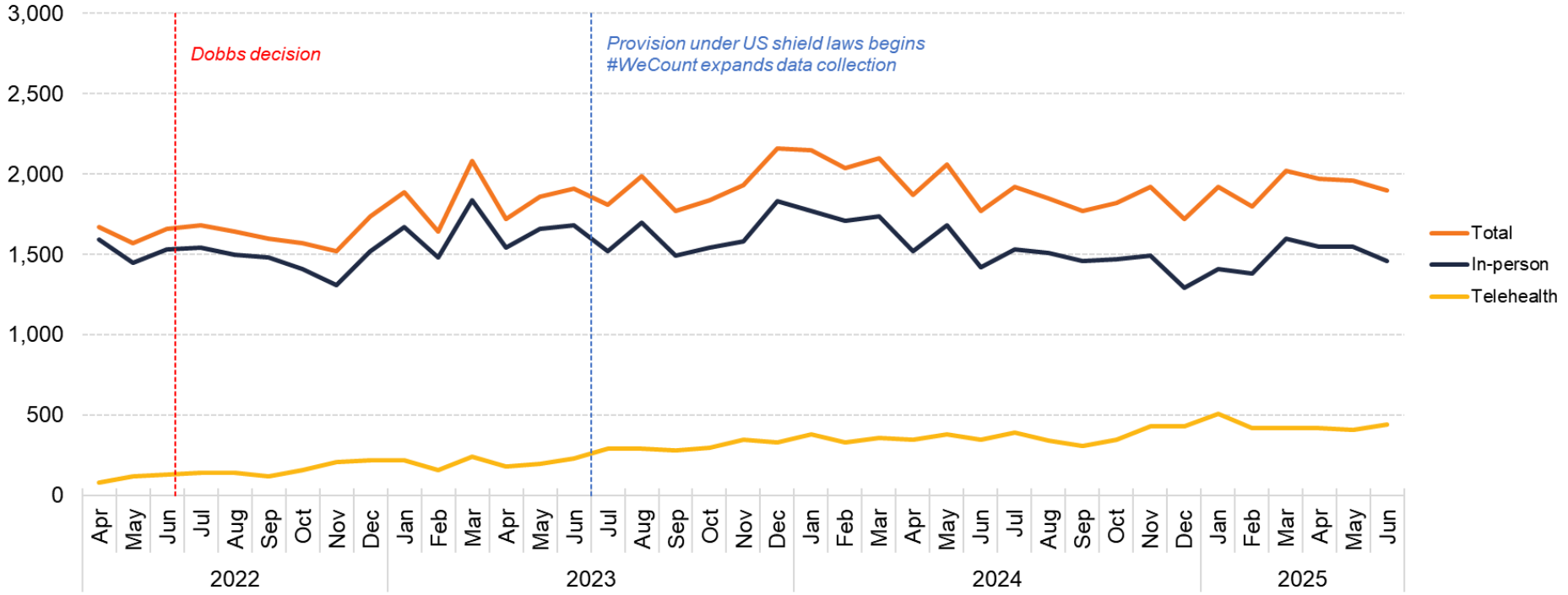
Maryland



Source: Society of Family Planning, December 2025

Massachusetts

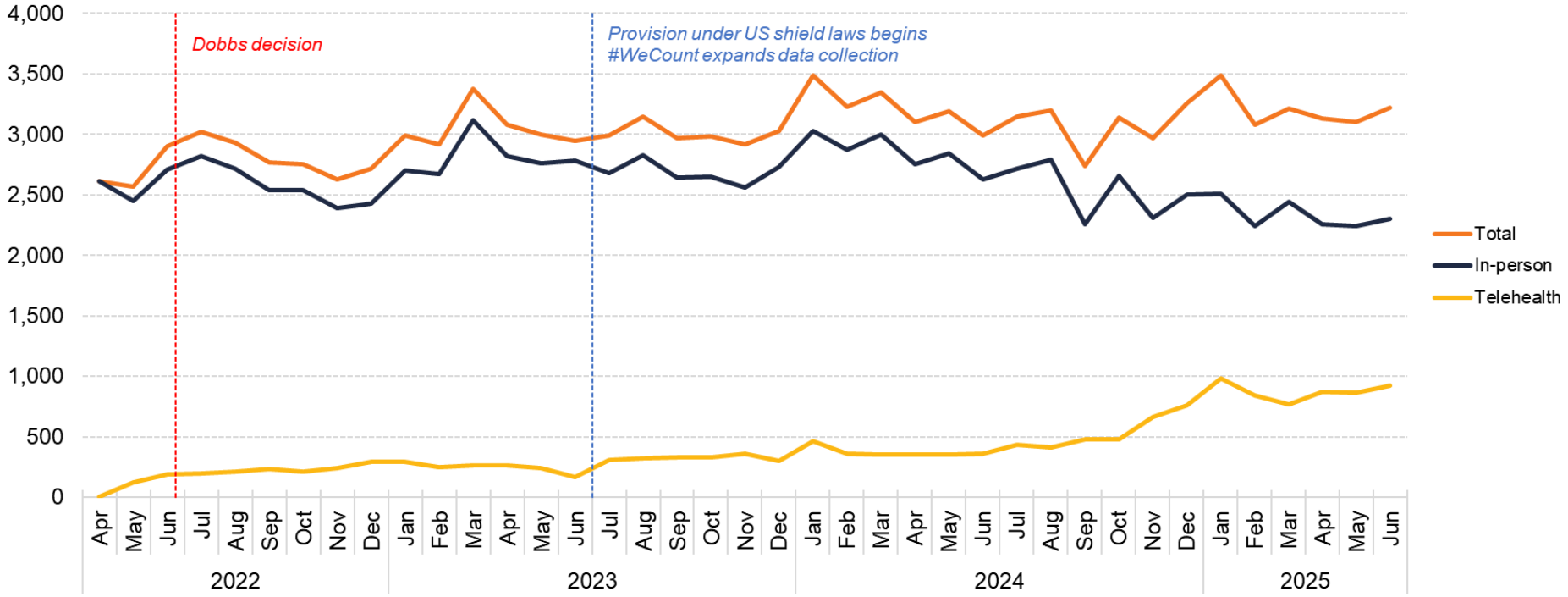
April 2022 to June 2025



Source: Society of Family Planning, December 2025

Michigan

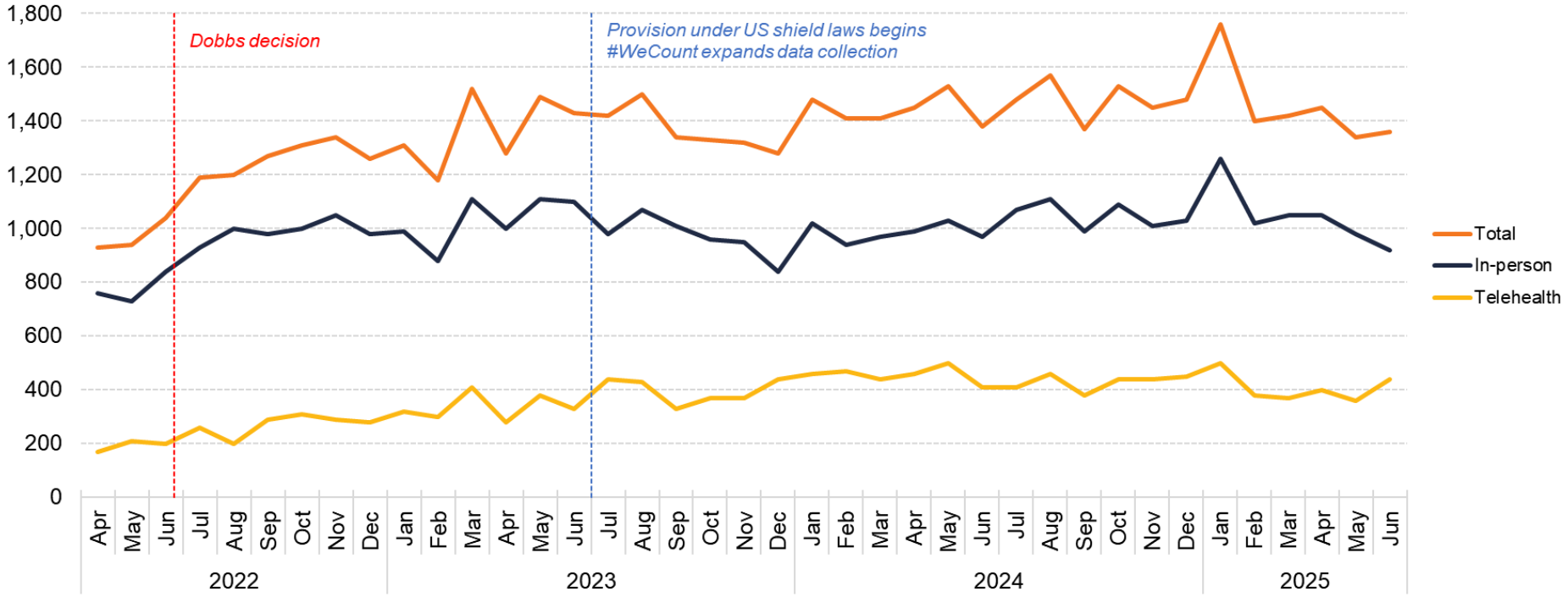
April 2022 to June 2025



Source: Society of Family Planning, December 2025

Minnesota

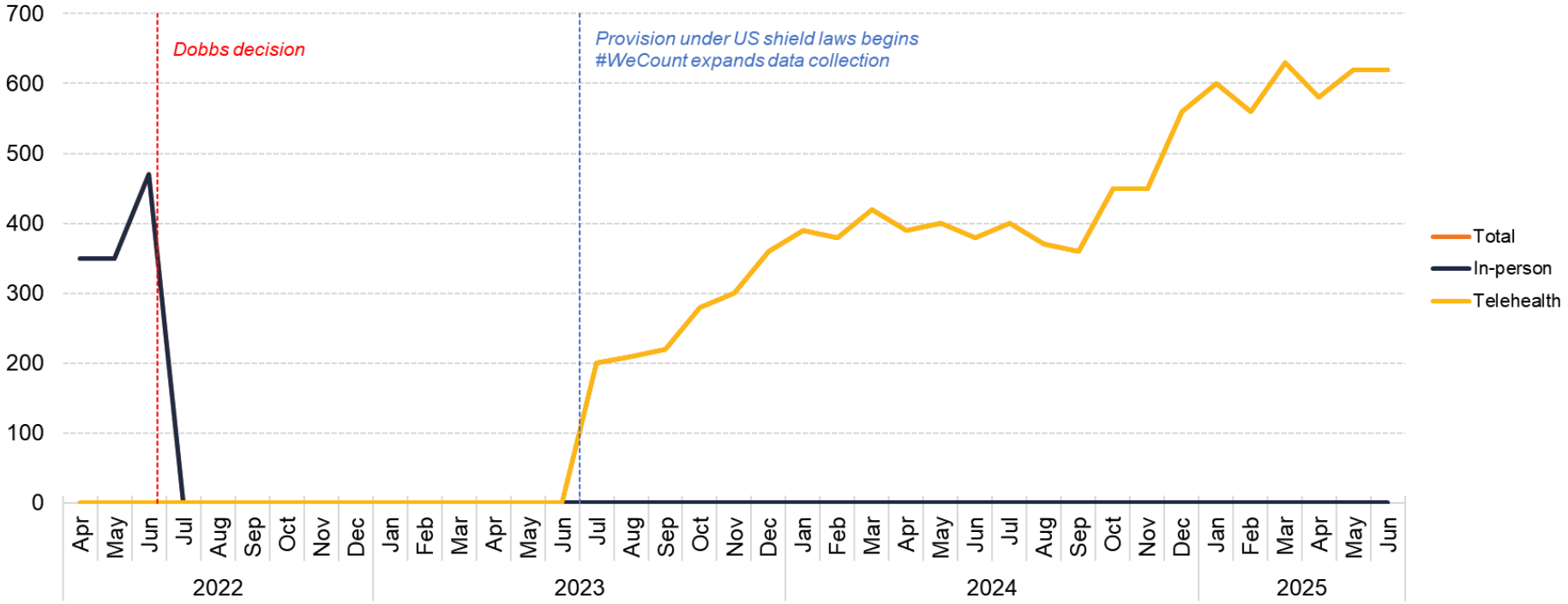
April 2022 to June 2025



Source: Society of Family Planning, December 2025

Mississippi

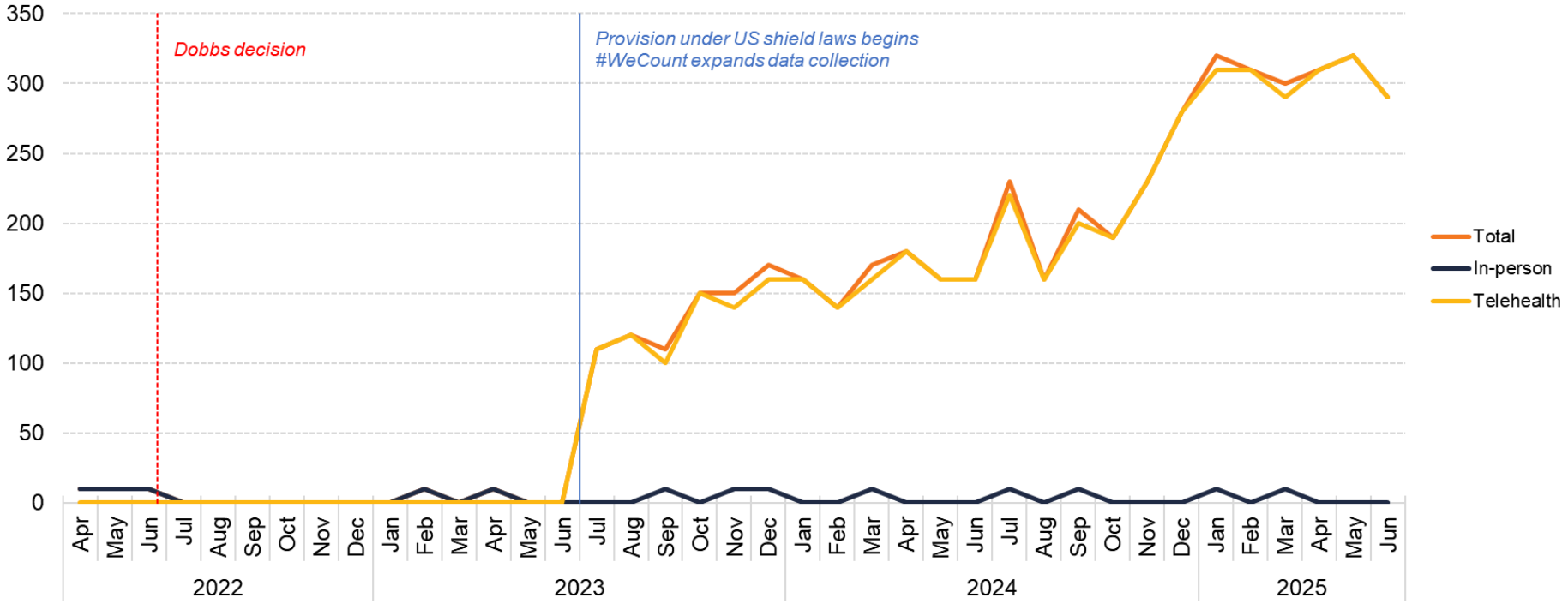
April 2022 to June 2025



Source: Society of Family Planning, December 2025

Missouri

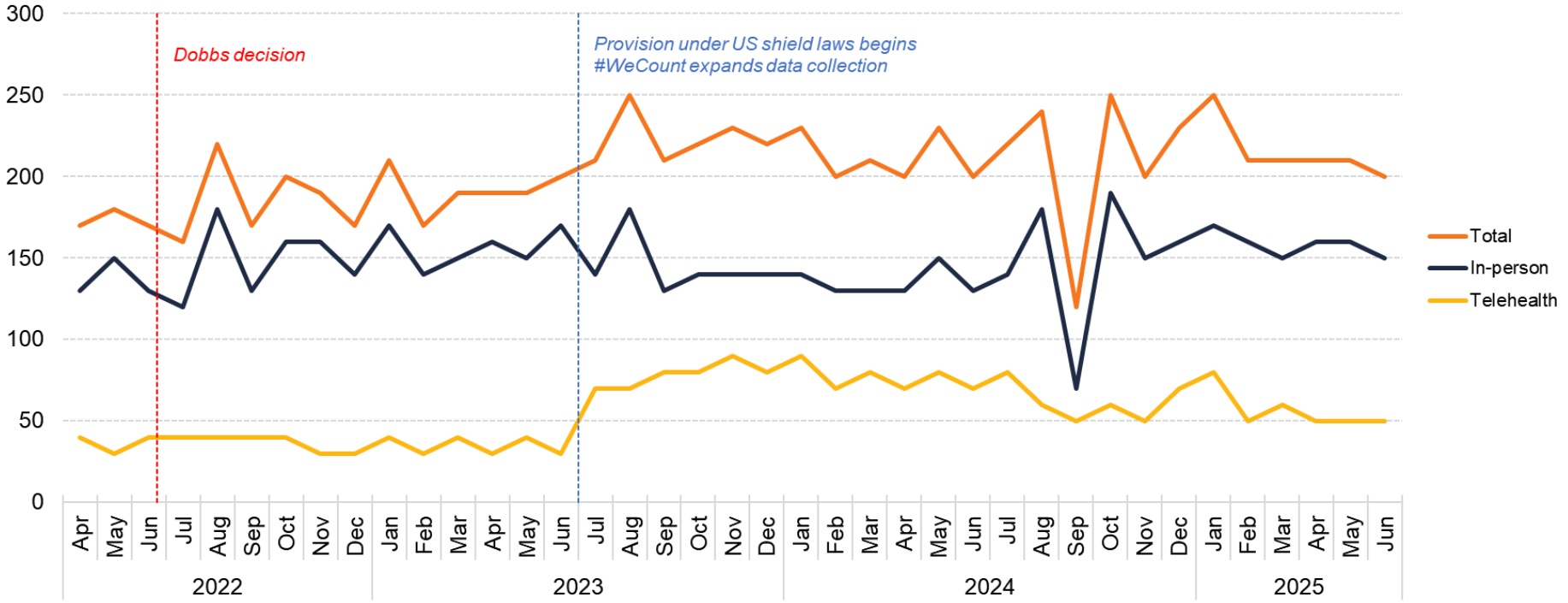
April 2022 to June 2025



Source: Society of Family Planning, December 2025

Montana

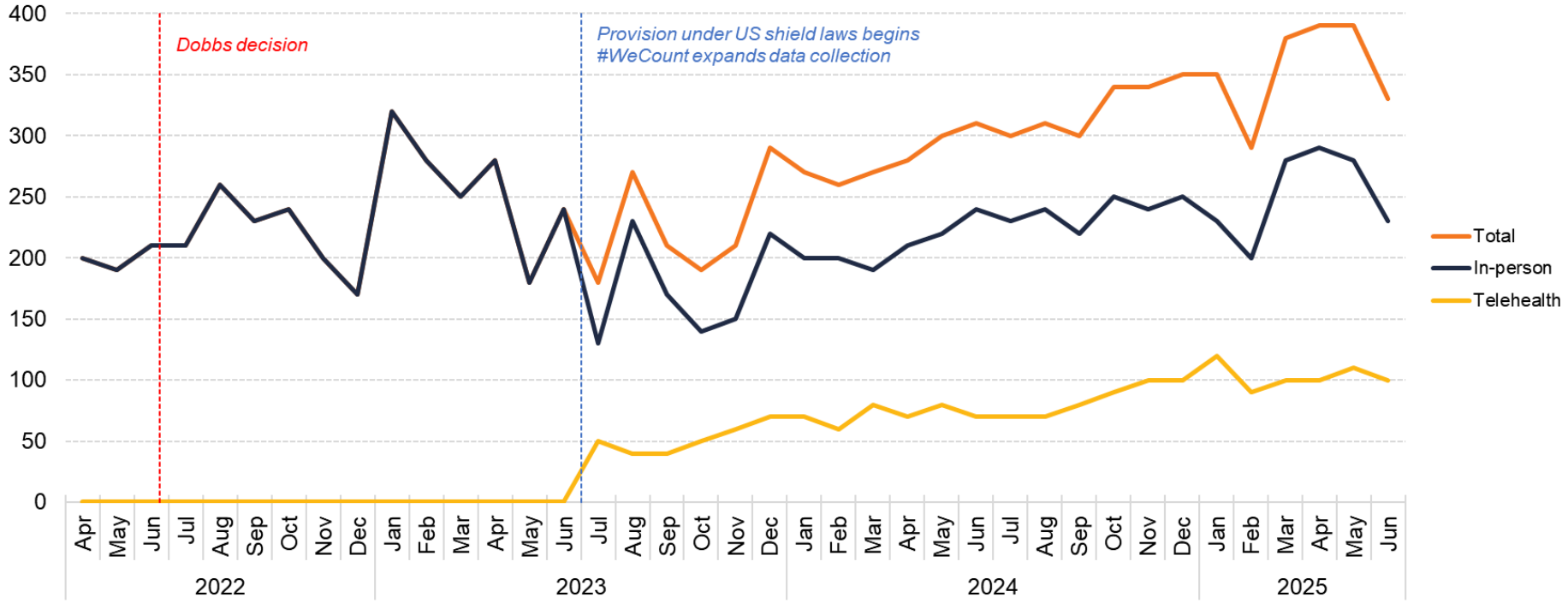
April 2022 to June 2025



Source: Society of Family Planning, December 2025

Nebraska

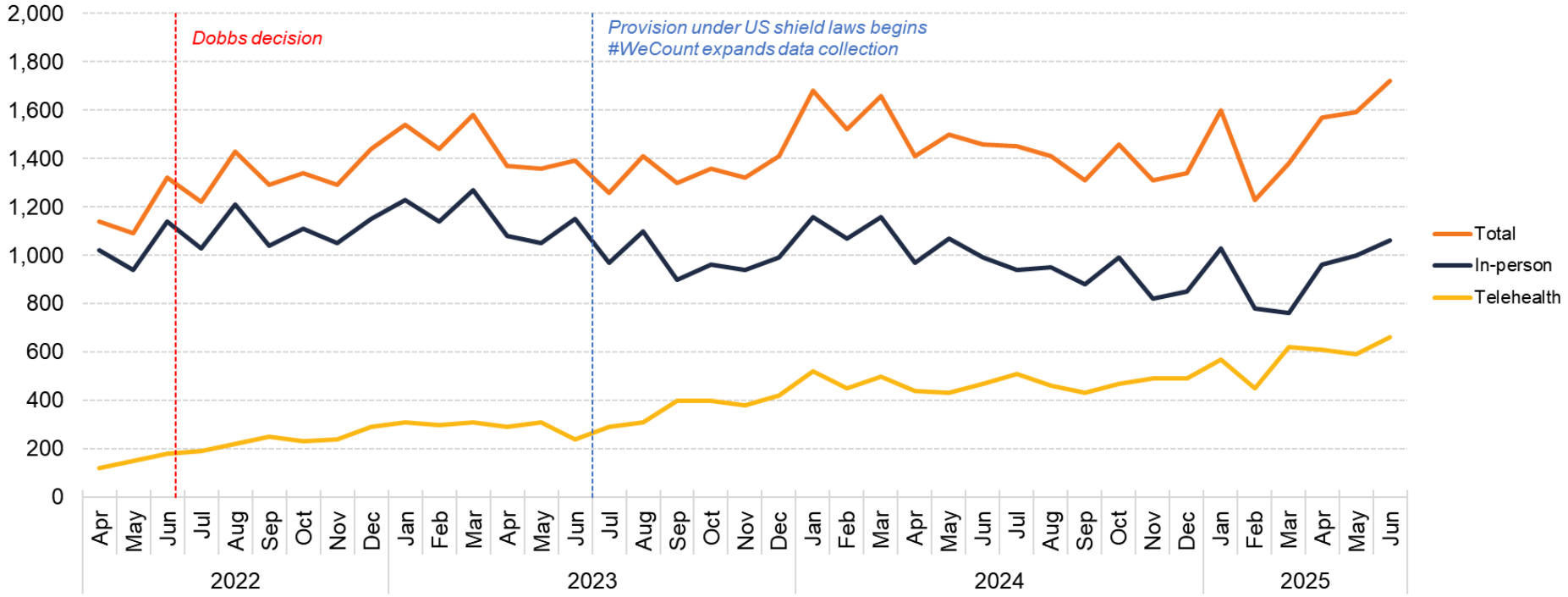
April 2022 to June 2025



Source: Society of Family Planning, December 2025

Nevada

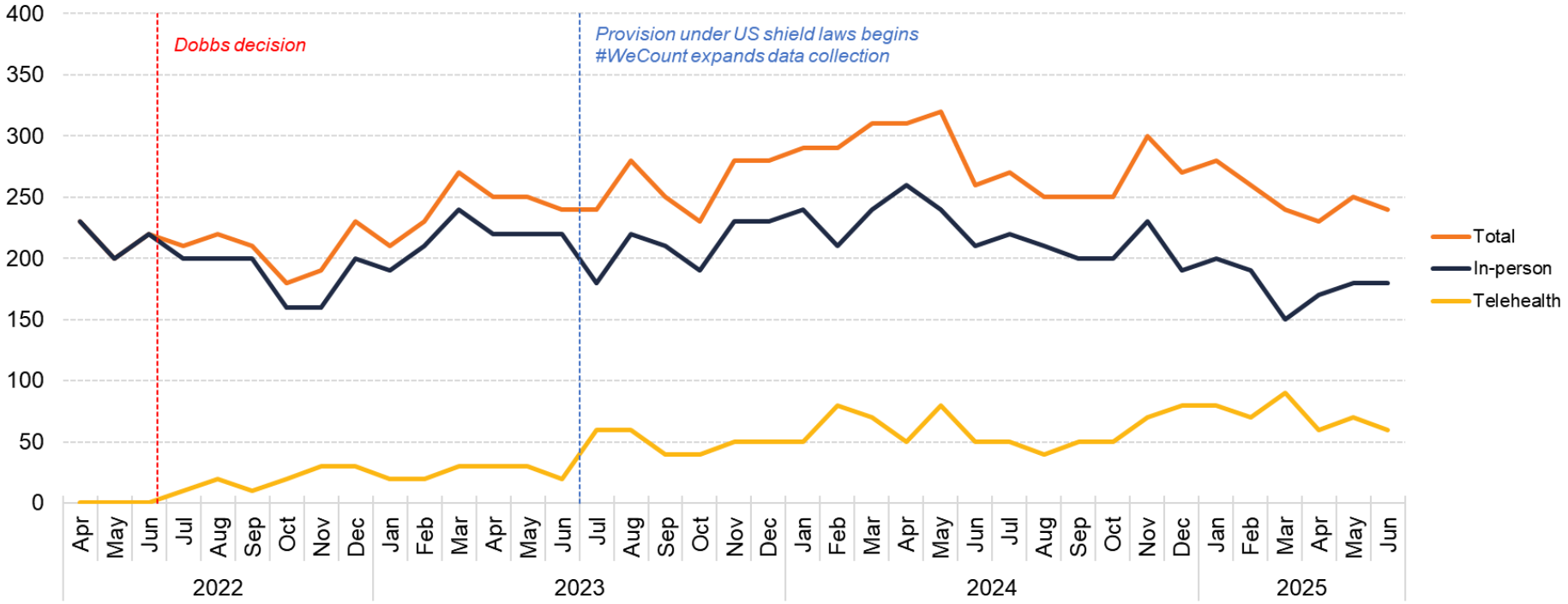
April 2022 to June 2025



Source: Society of Family Planning, December 2025

New Hampshire

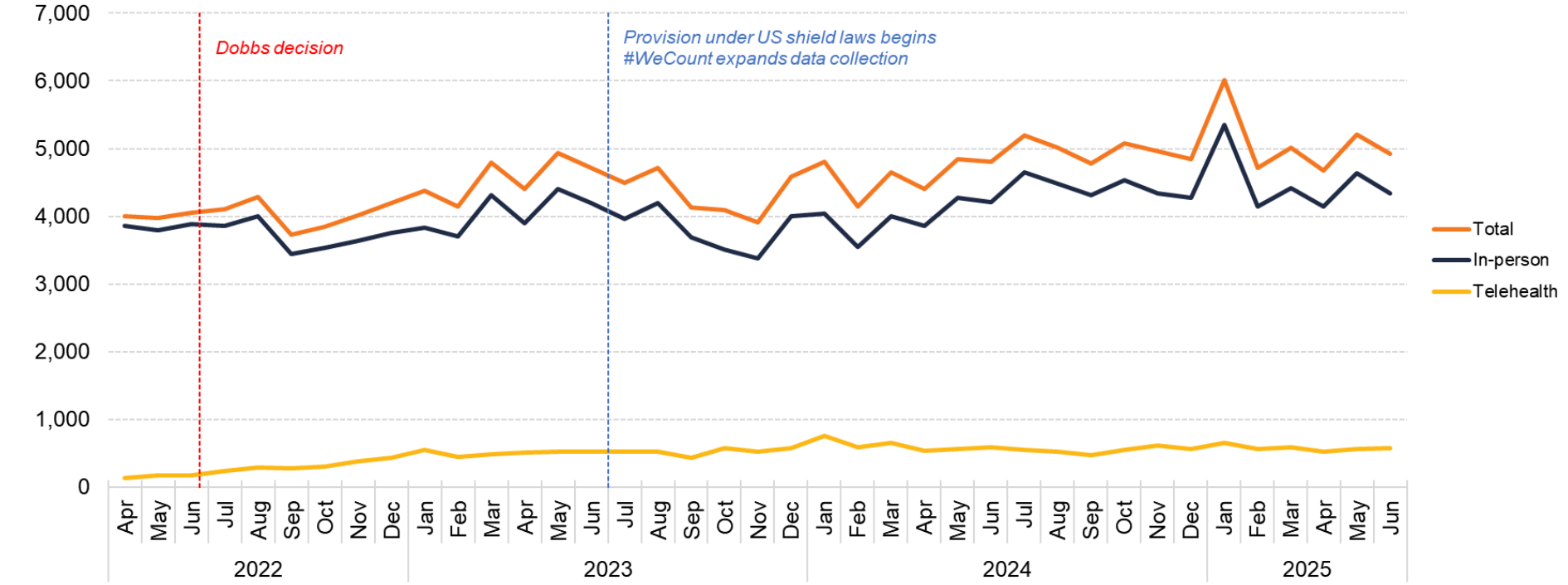
April 2022 to June 2025



Source: Society of Family Planning, December 2025

New Jersey

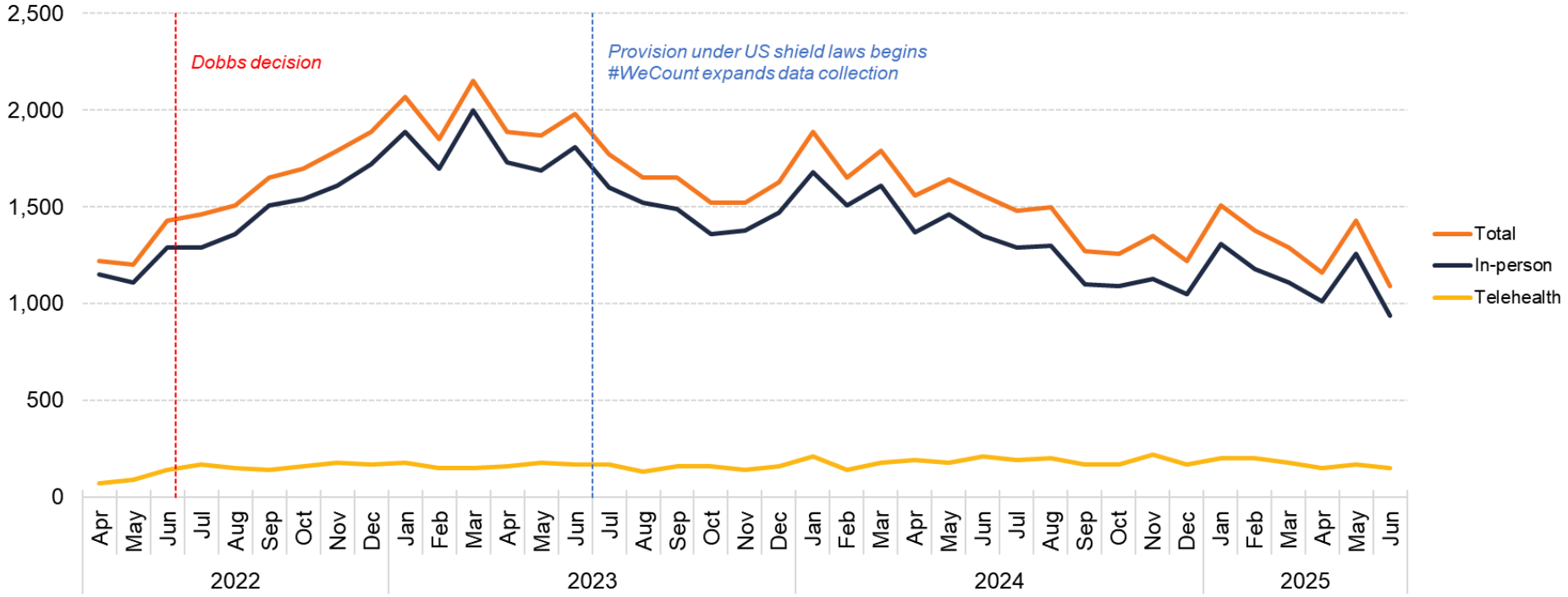
April 2022 to June 2025



Source: Society of Family Planning, December 2025

New Mexico

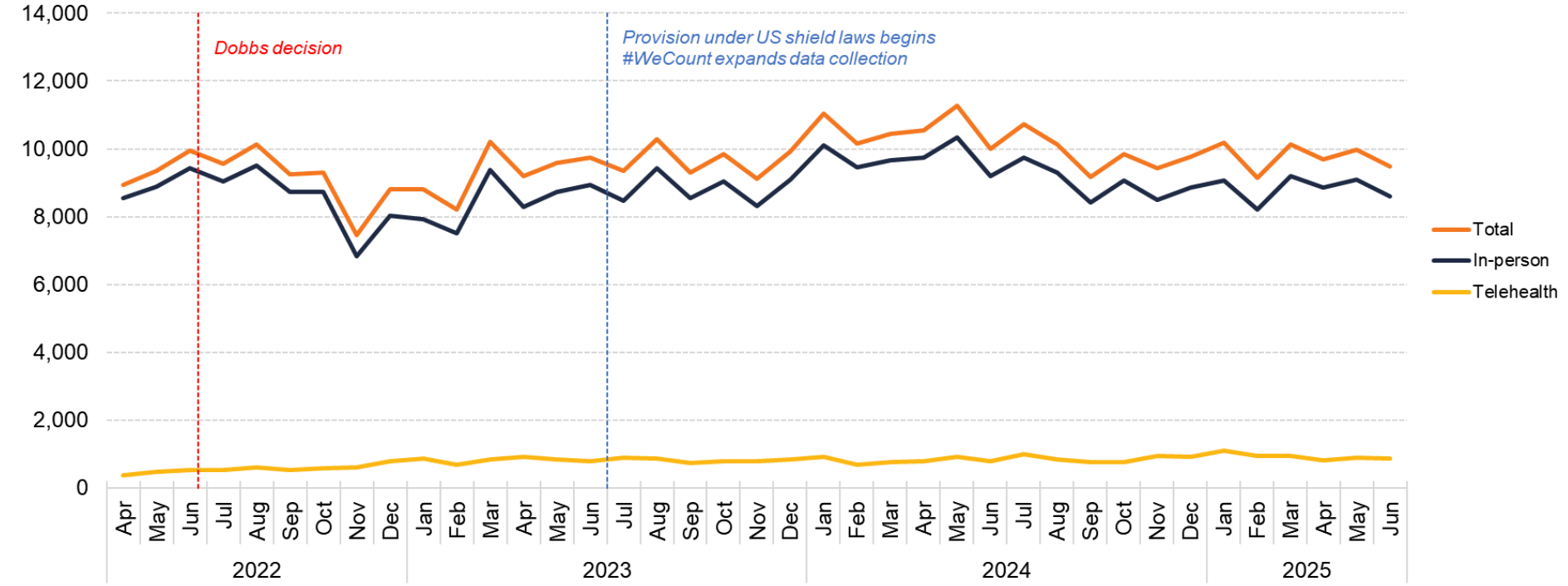
April 2022 to June 2025



Source: Society of Family Planning, December 2025

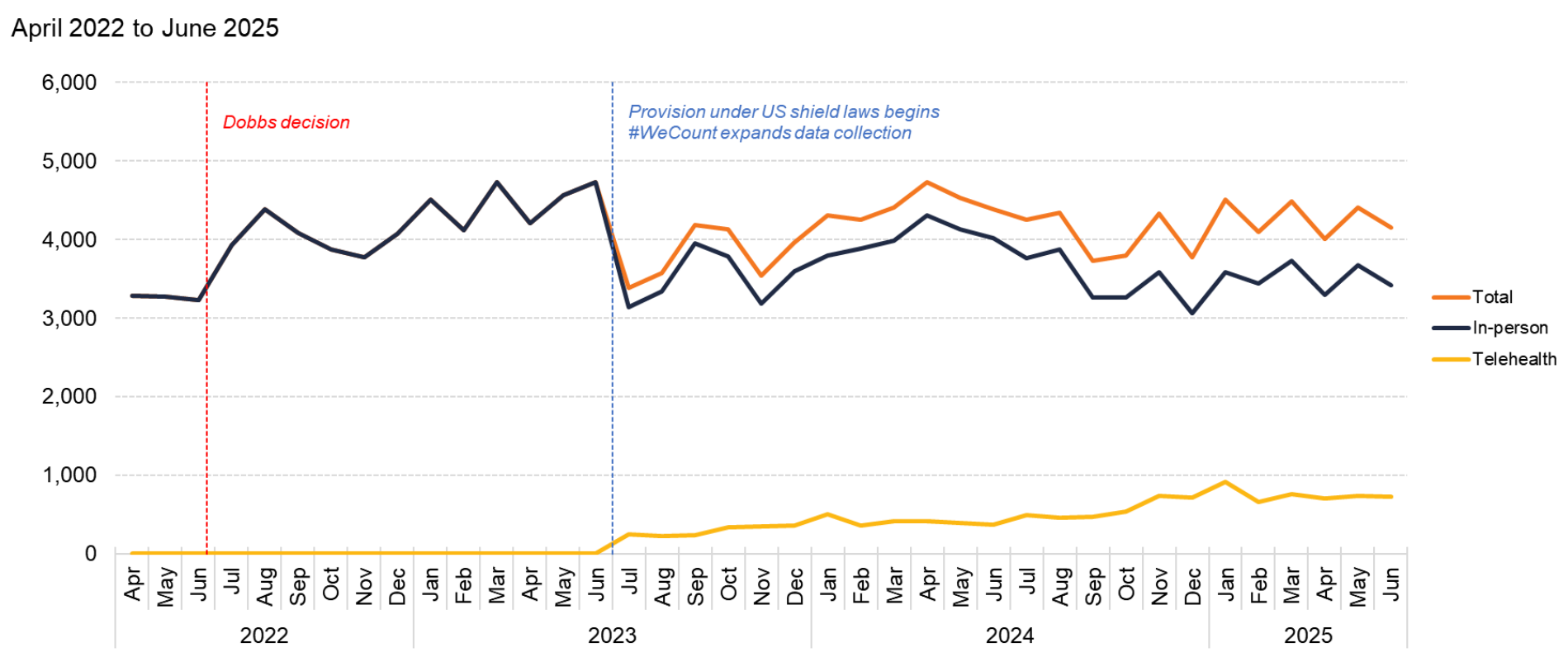
New York

April 2022 to June 2025



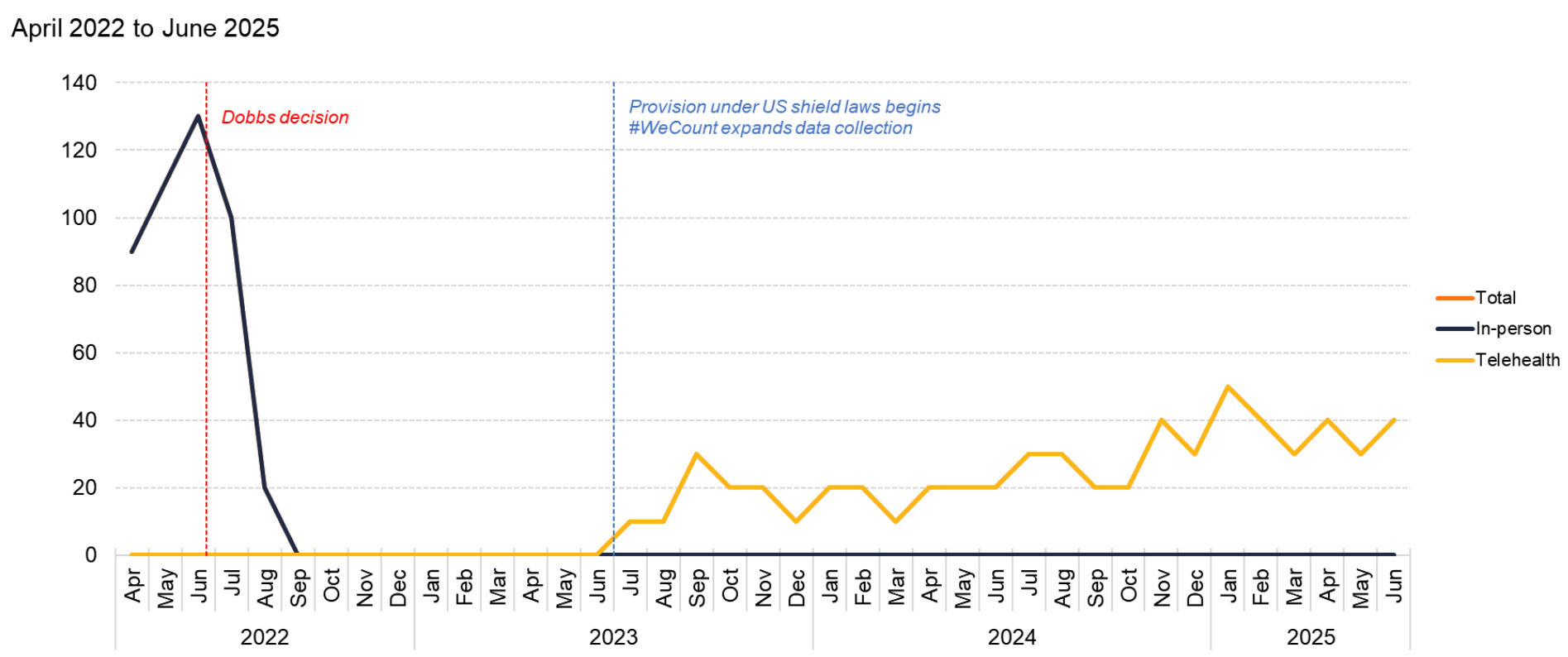
Source: Society of Family Planning, December 2025

North Carolina



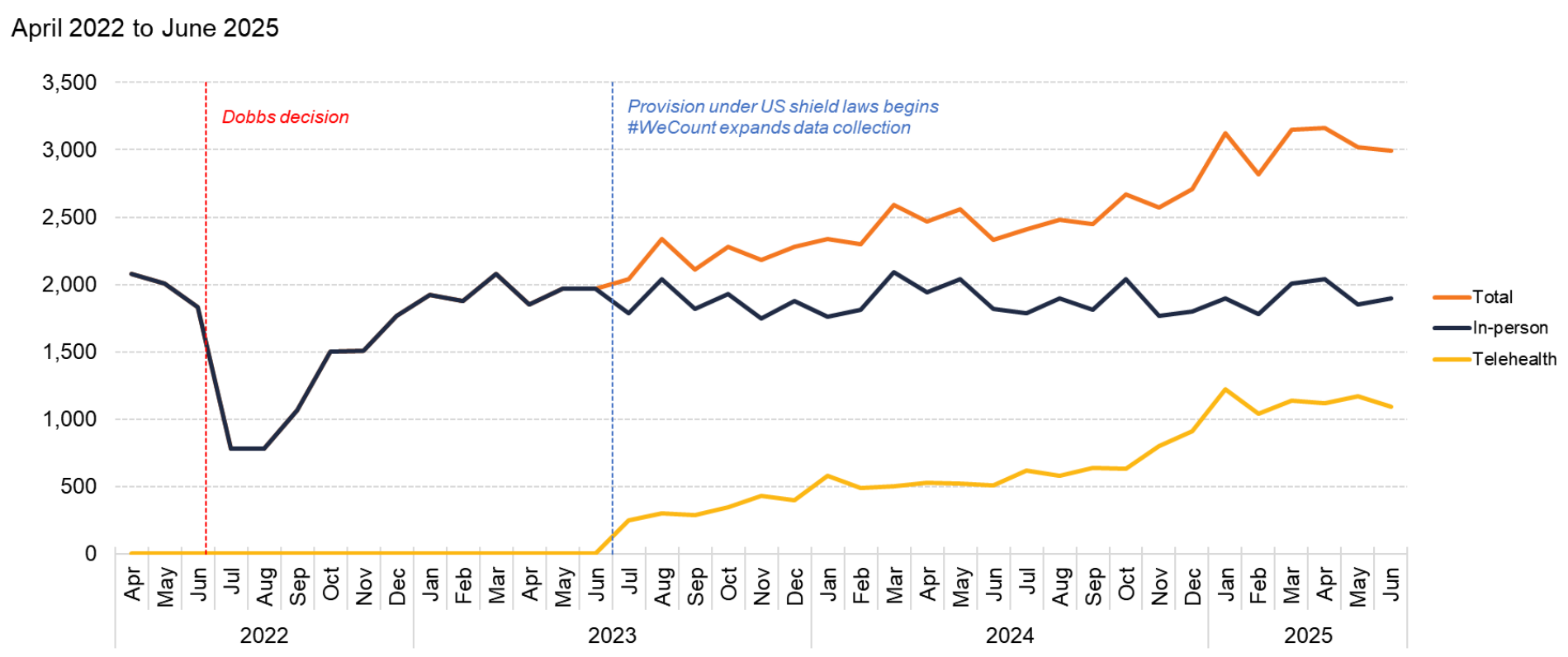
Source: Society of Family Planning, December 2025

North Dakota



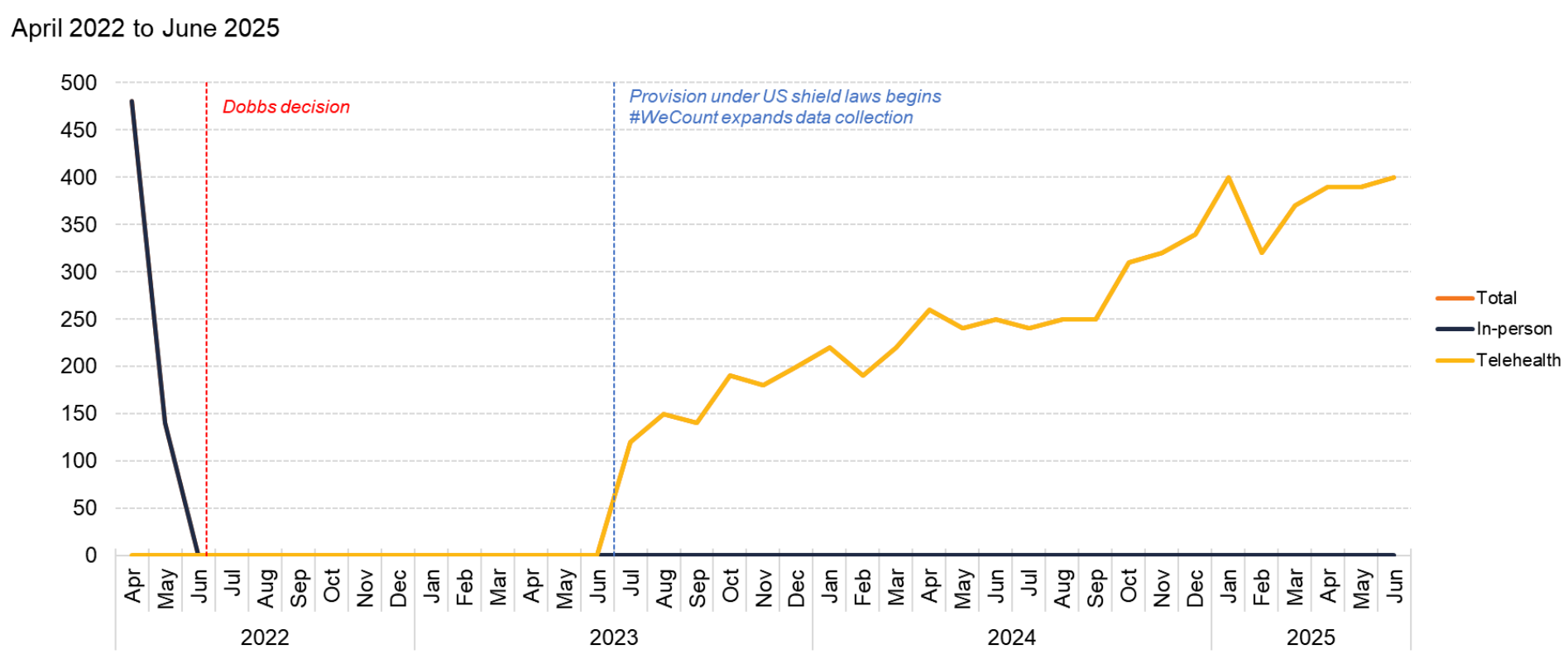
Source: Society of Family Planning, December 2025

Ohio



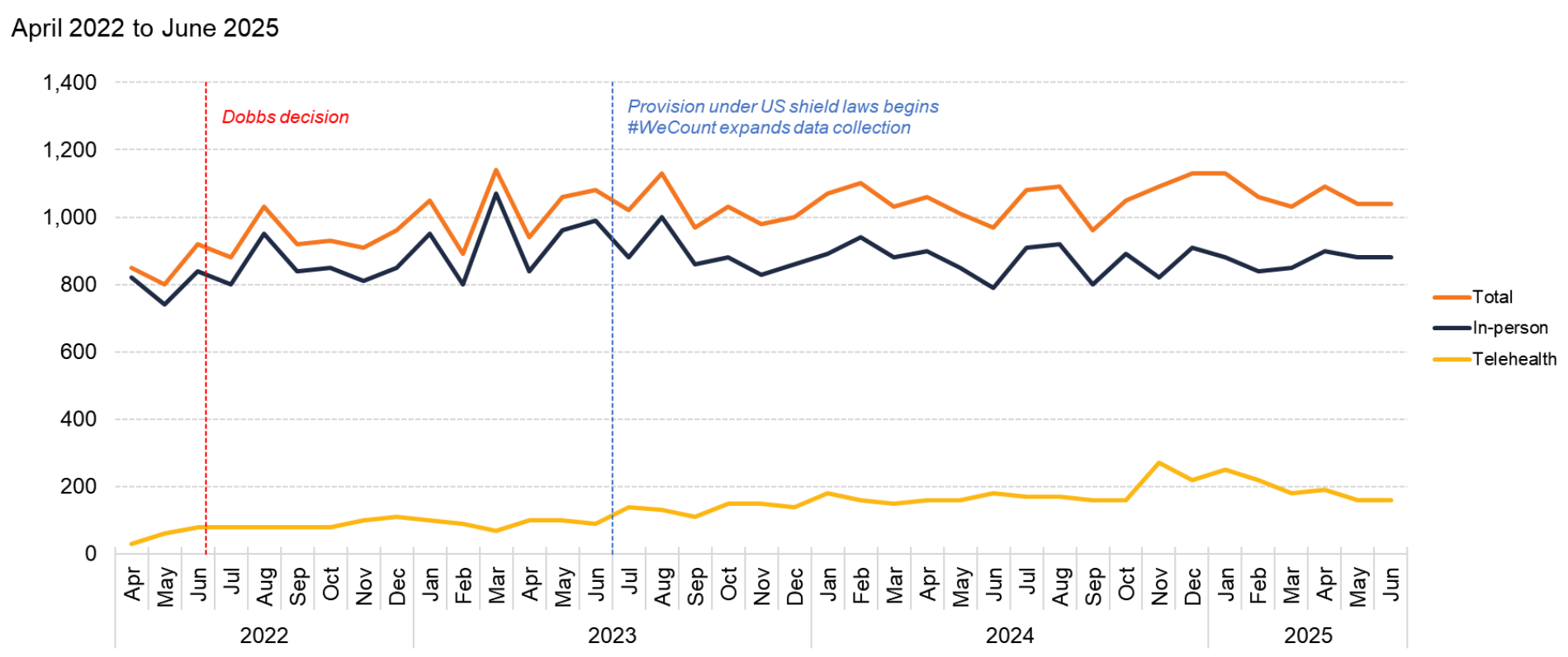
Source: Society of Family Planning, December 2025

Oklahoma



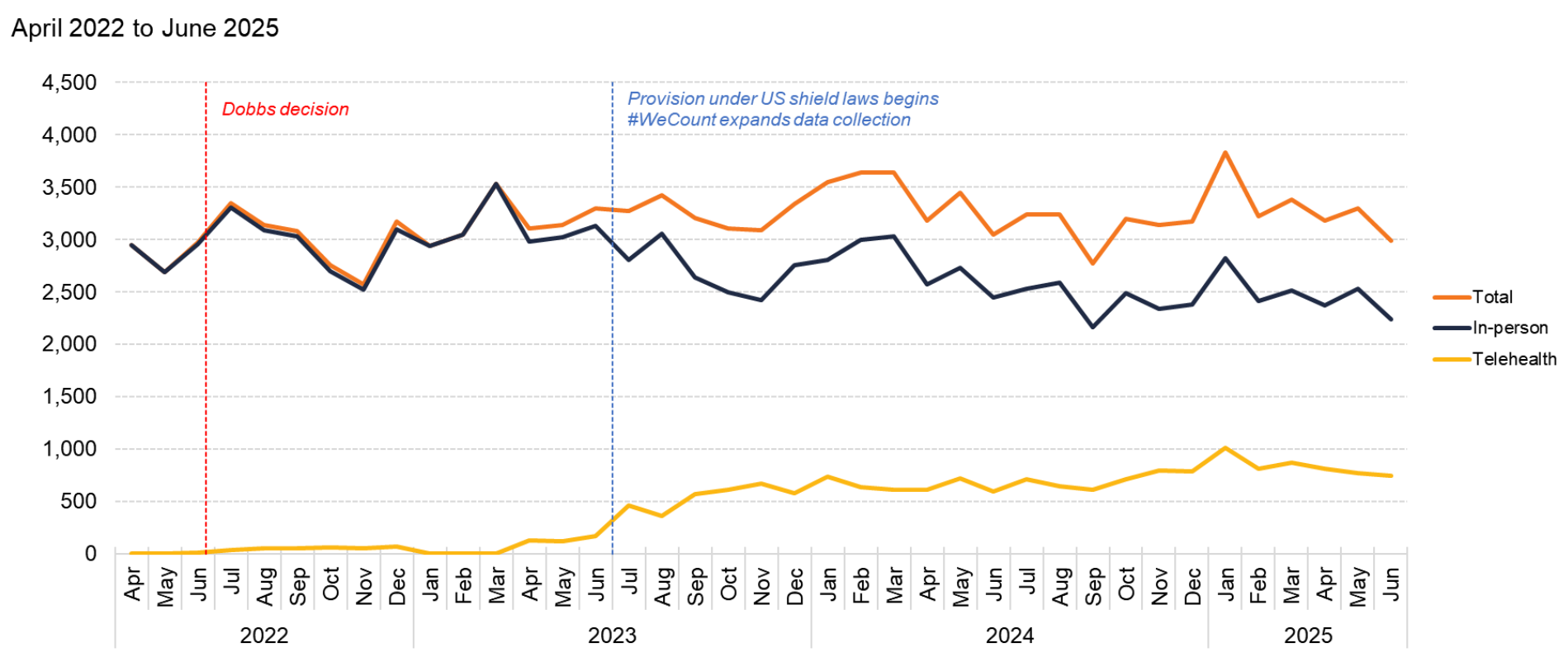
Source: Society of Family Planning, December 2025

Oregon



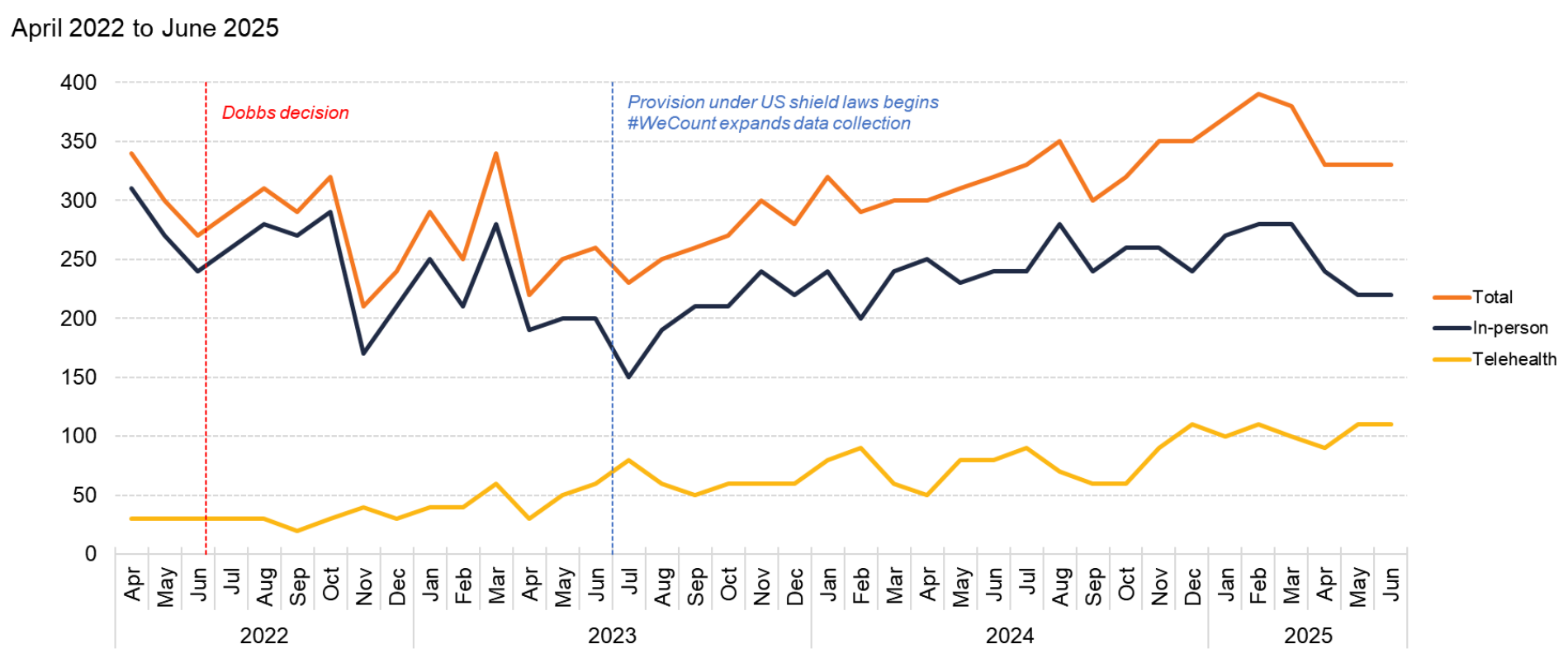
Source: Society of Family Planning, December 2025

Pennsylvania



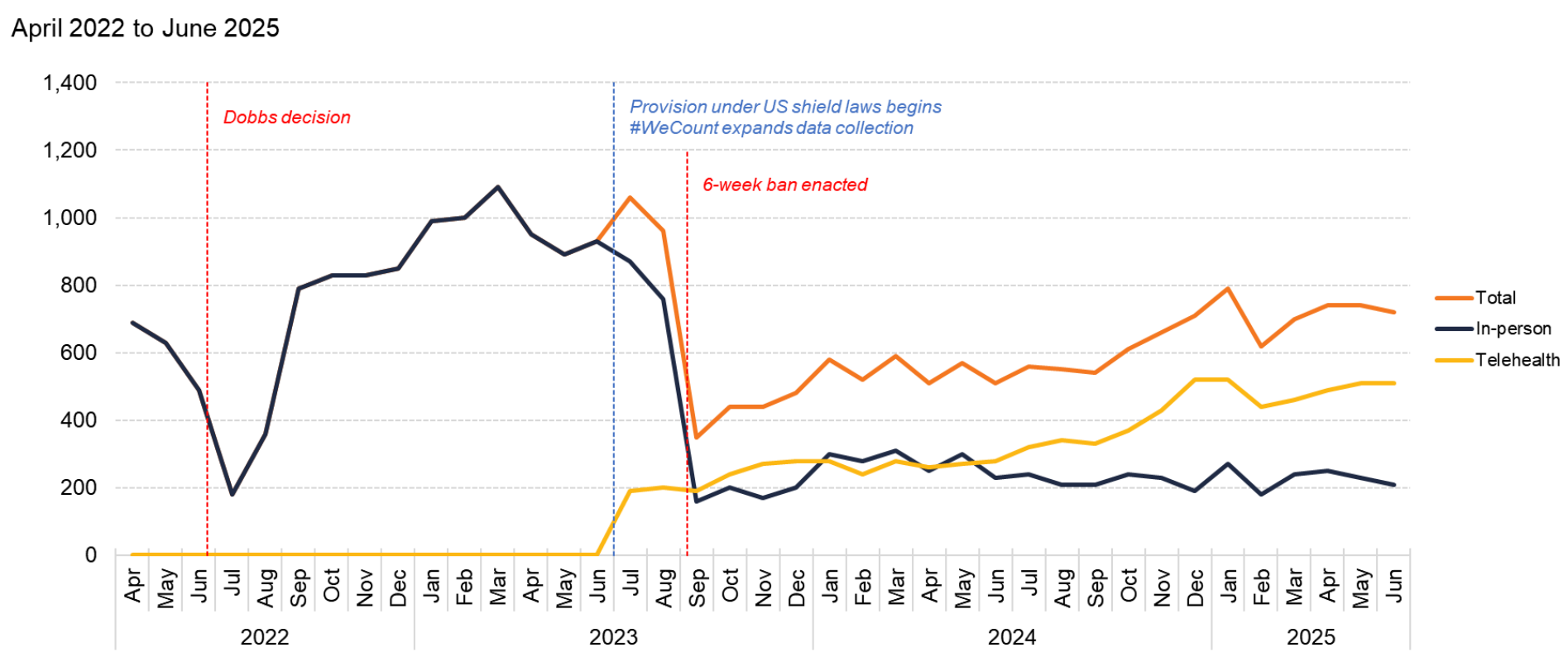
Source: Society of Family Planning, December 2025

Rhode Island



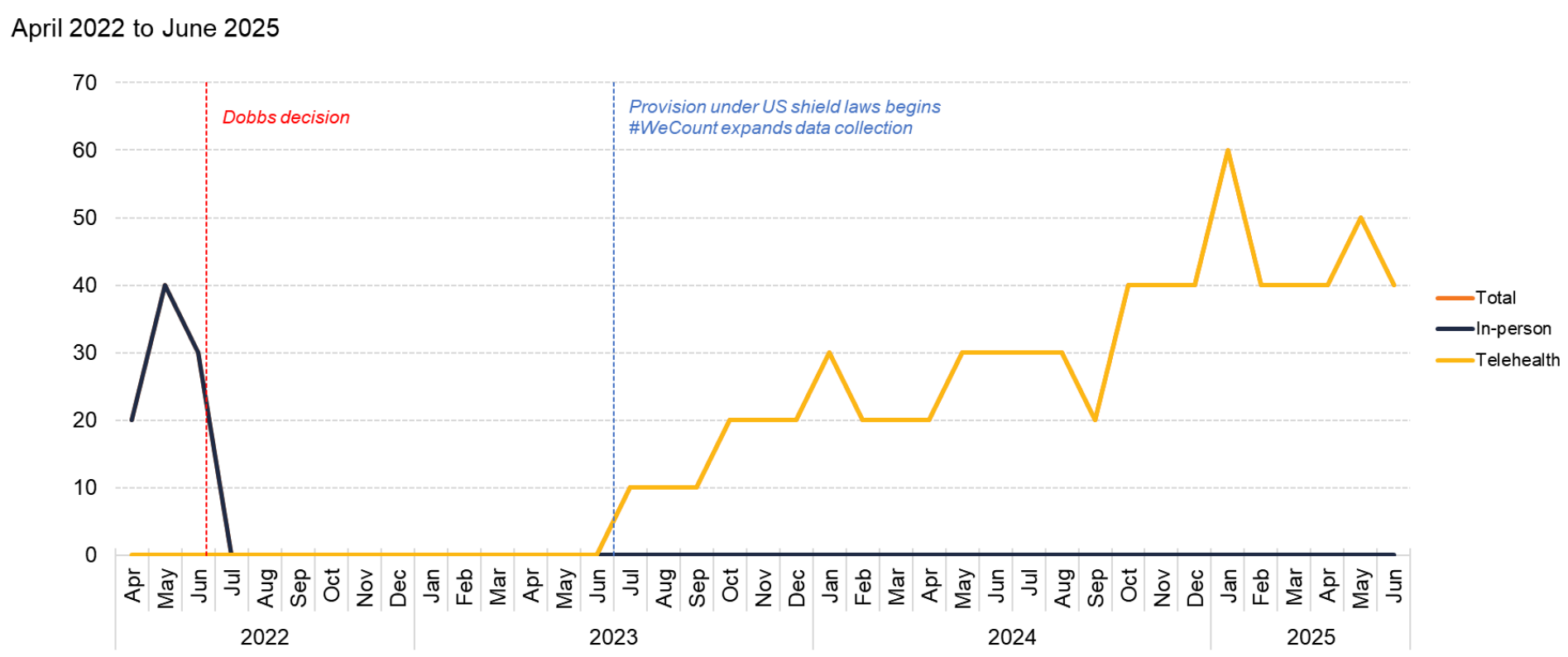
Source: Society of Family Planning, December 2025

South Carolina



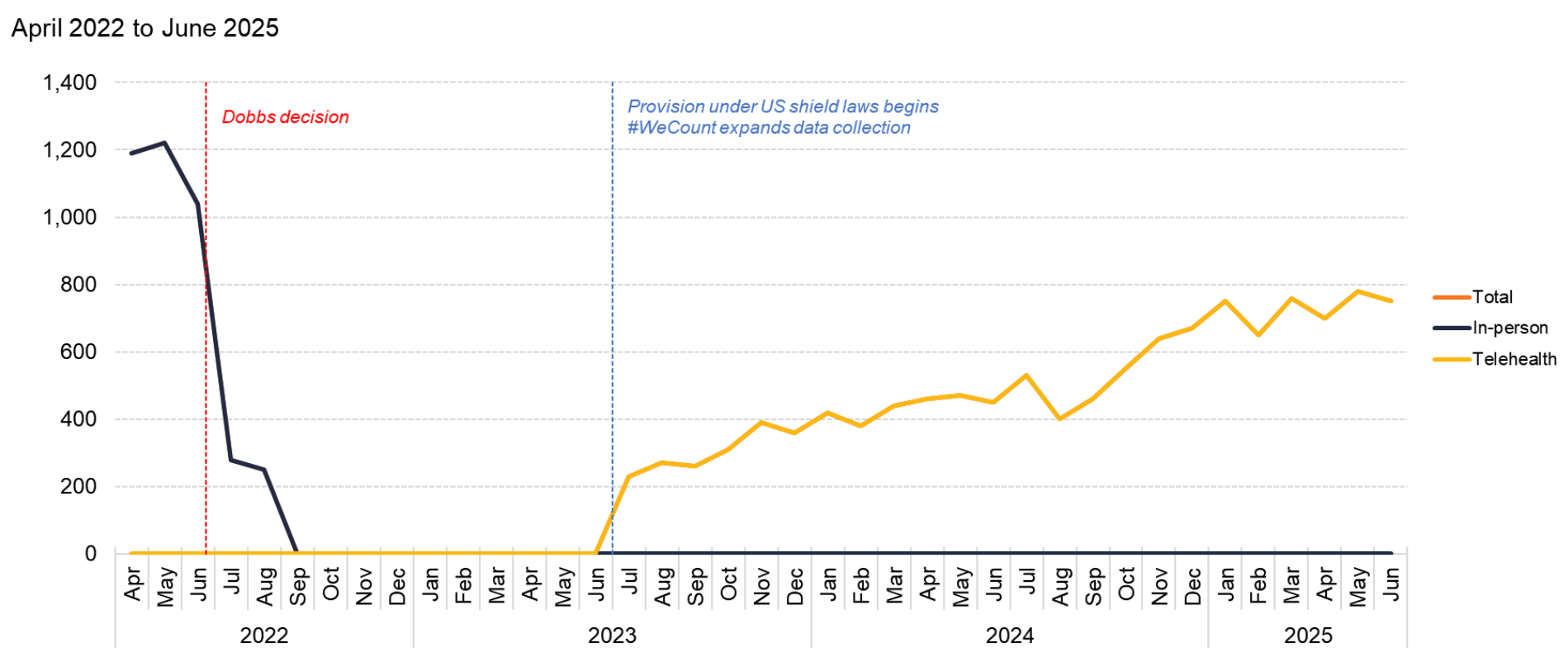
Source: Society of Family Planning, December 2025

South Dakota



Source: Society of Family Planning, December 2025

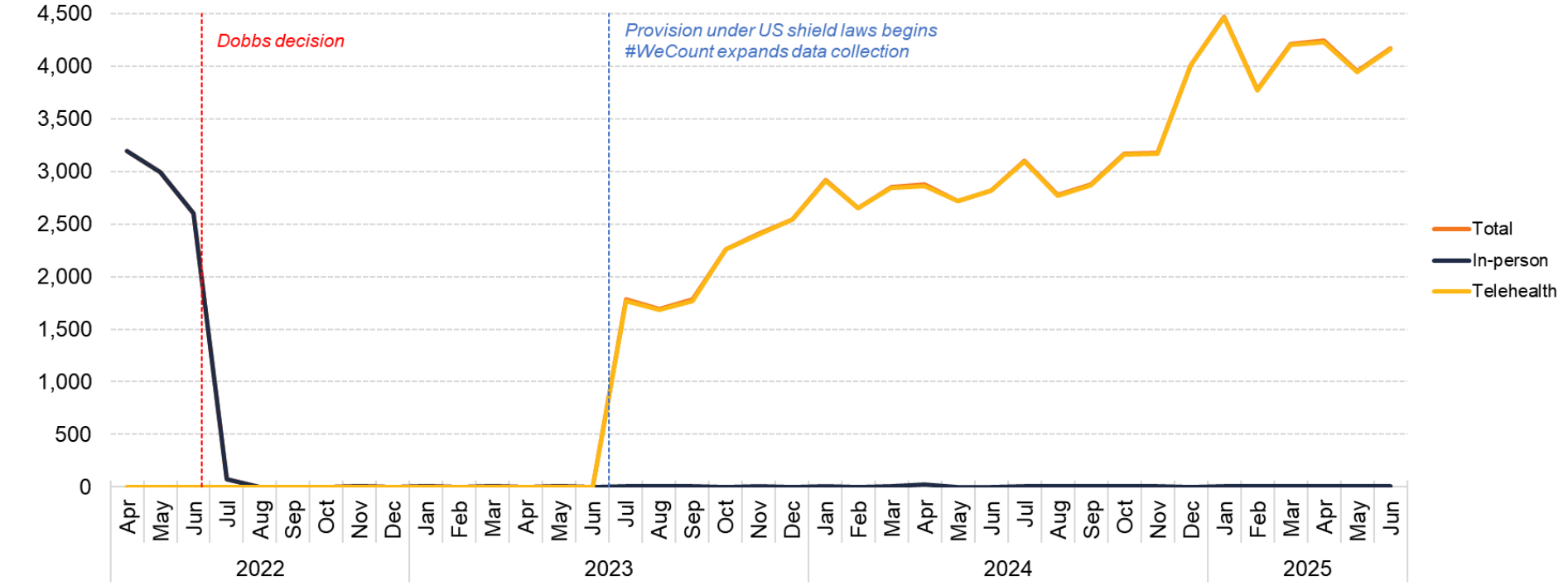
Tennessee



Source: Society of Family Planning, December 2025

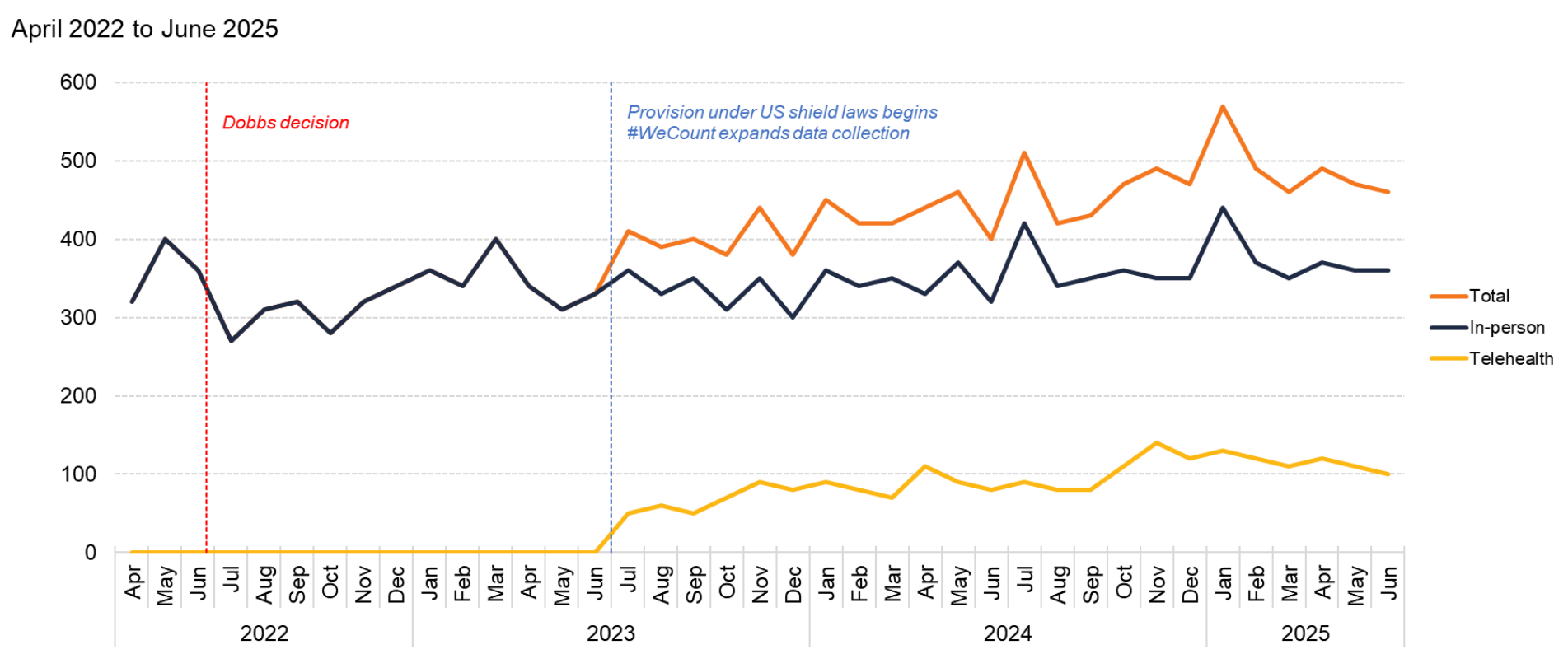
Texas

April 2022 to June 2025



Source: Society of Family Planning, December 2025

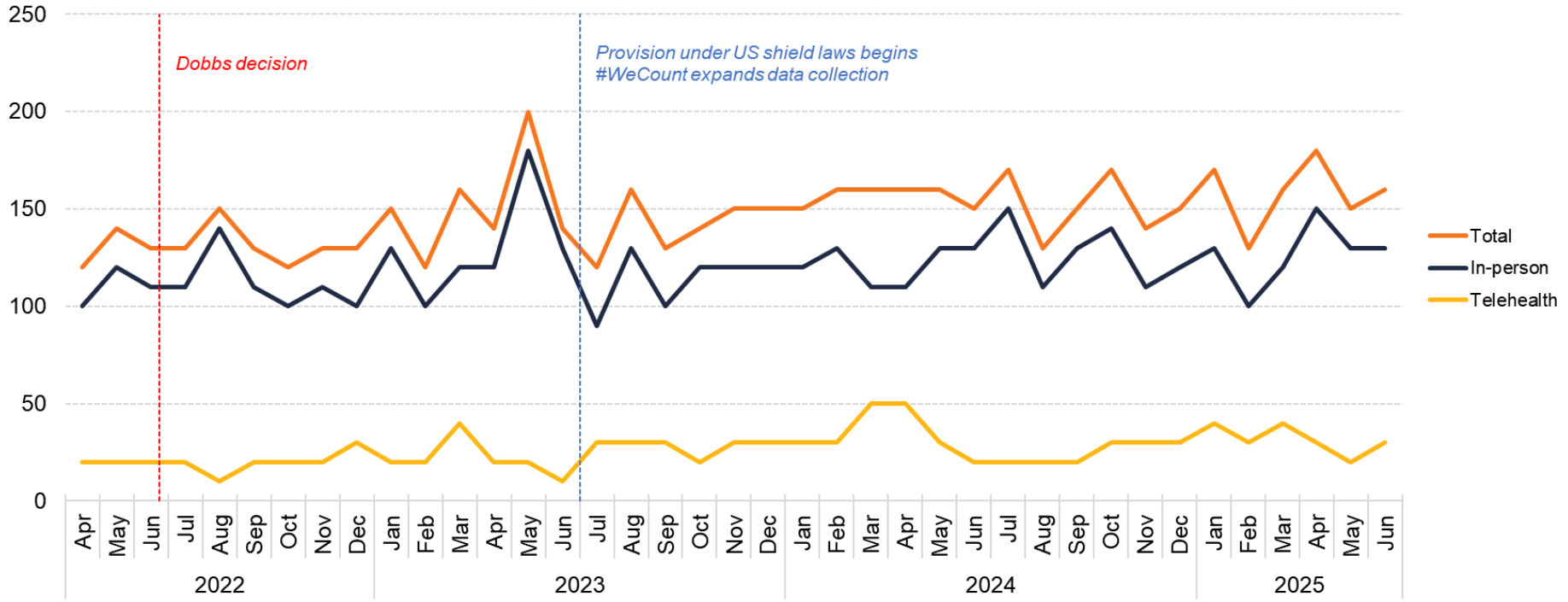
Utah



Source: Society of Family Planning, December 2025

Vermont

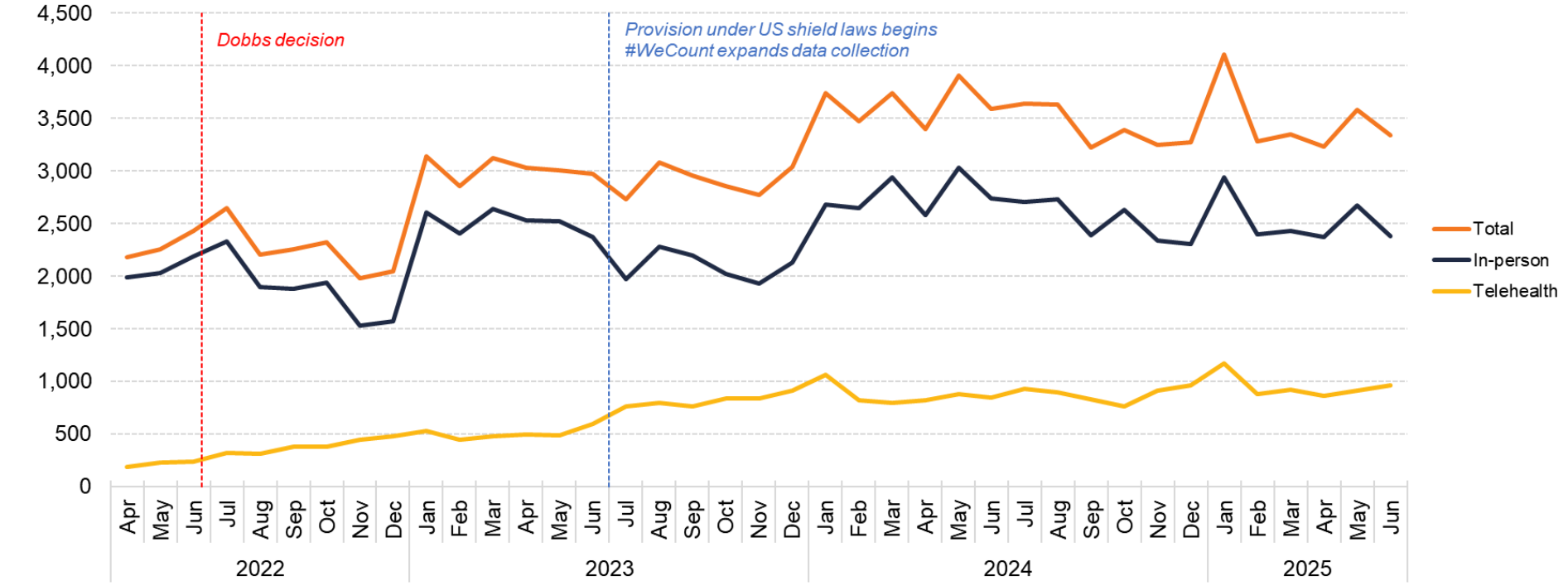
April 2022 to June 2025



Source: Society of Family Planning, December 2025

Virginia

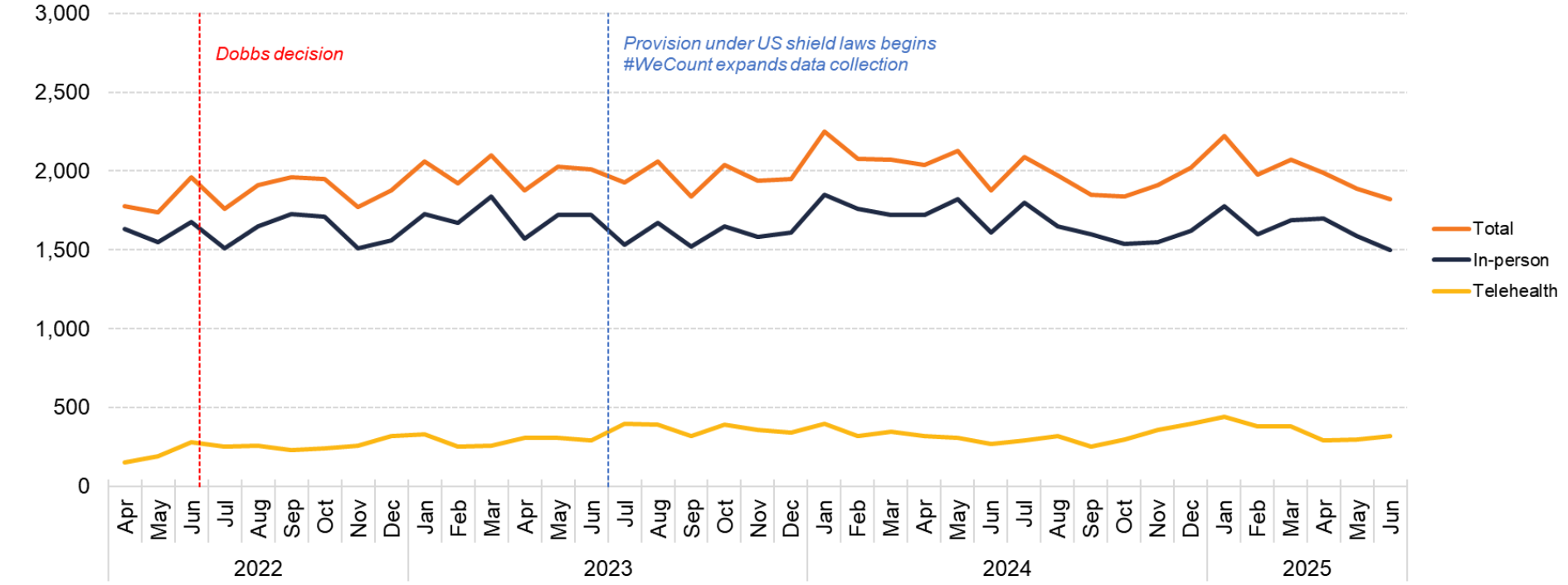
April 2022 to June 2025



Source: Society of Family Planning, December 2025

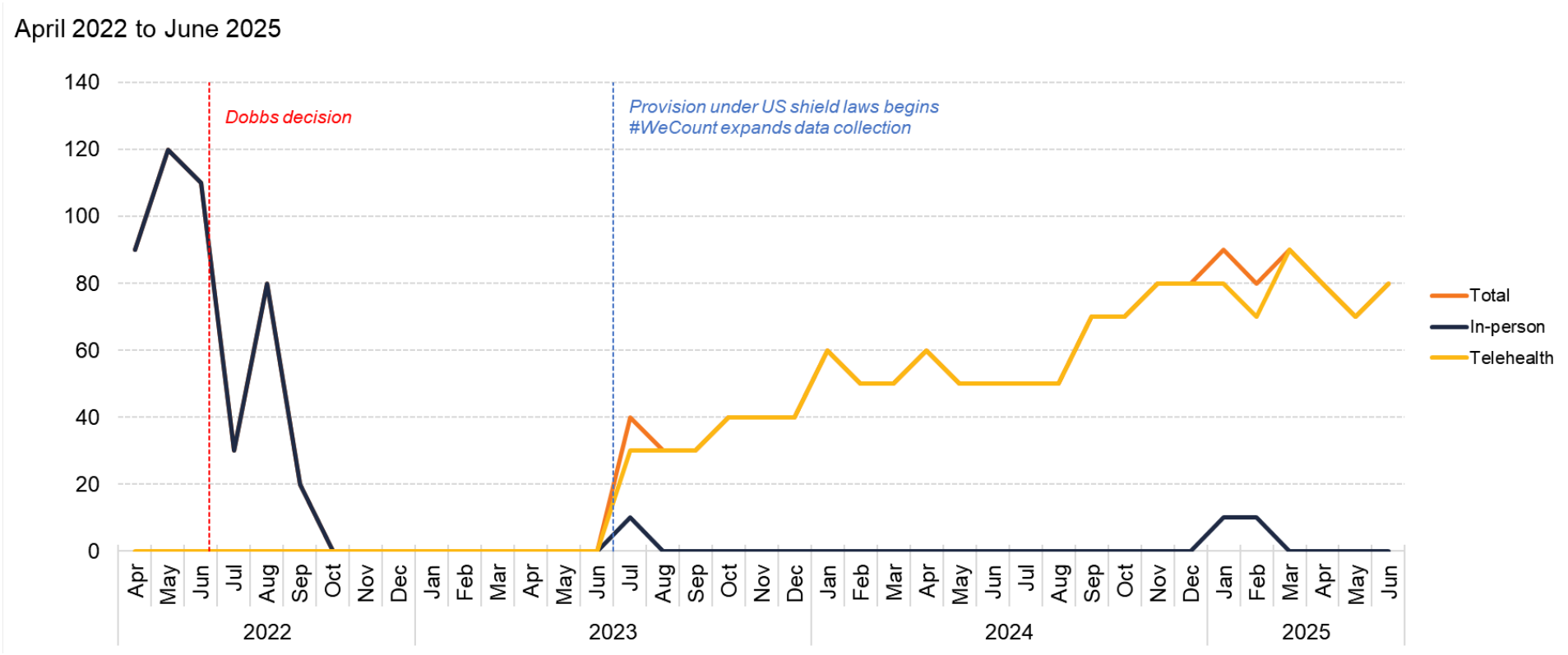
Washington

April 2022 to June 2025



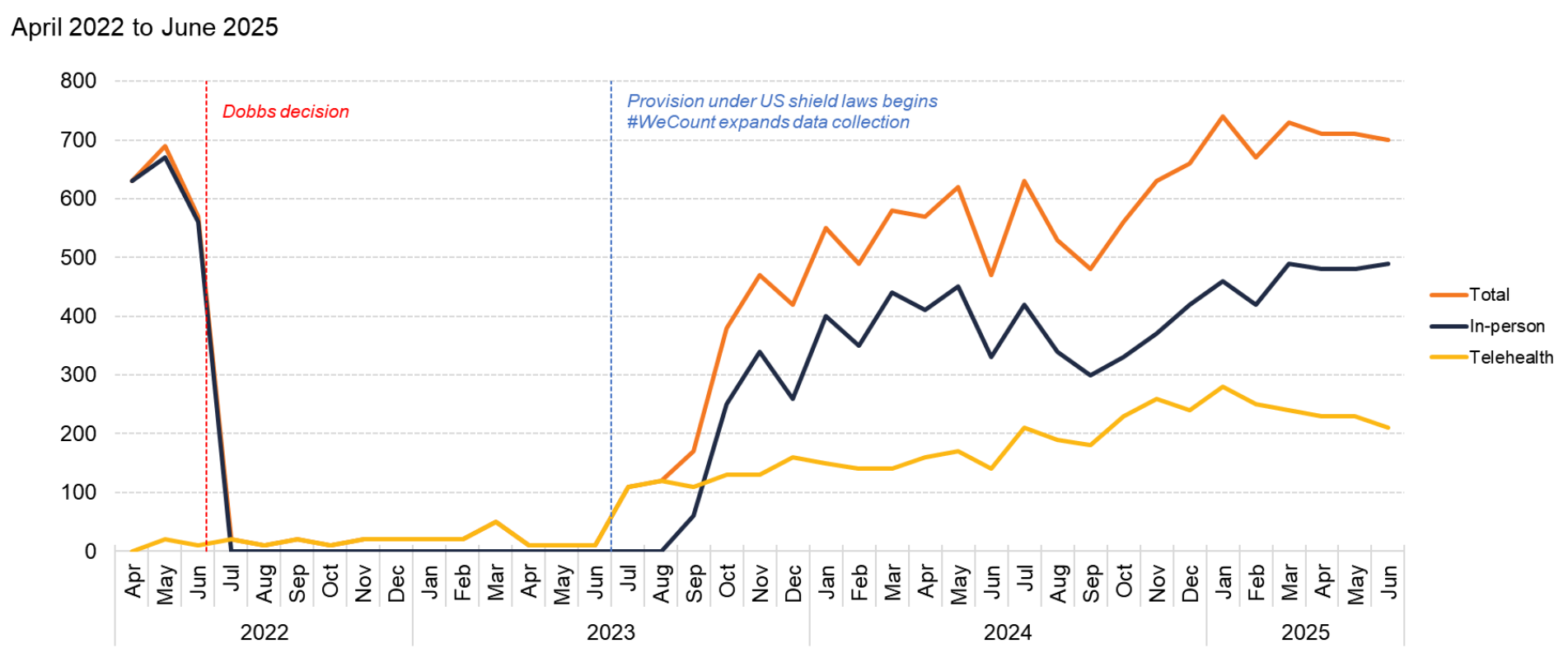
Source: Society of Family Planning, December 2025

West Virginia



Source: Society of Family Planning, December 2025

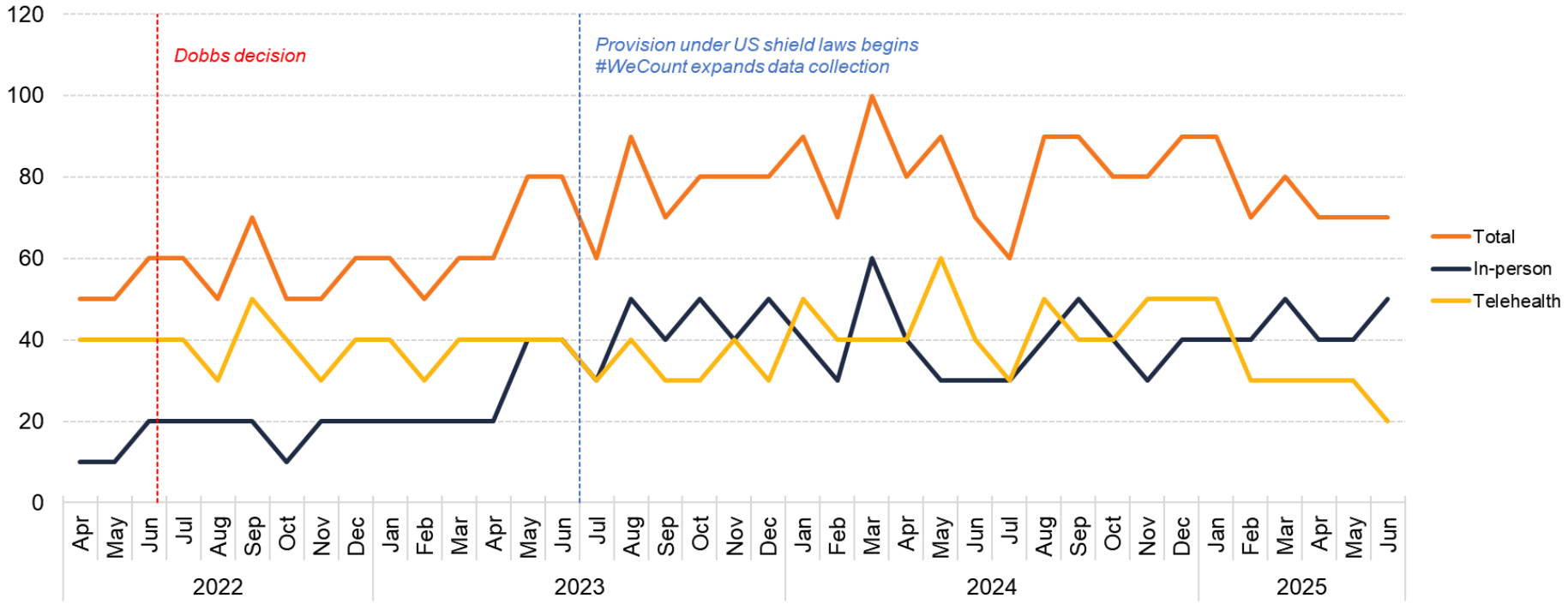
Wisconsin



Source: Society of Family Planning, December 2025

Wyoming

April 2022 to June 2025



Source: Society of Family Planning, December 2025

EXHIBIT 3

Abigail R. A. Aiken et al., Research Letter,
***Provision of Abortion Medications Using Online Asynchronous Telemedicine Under Shield Laws in the US*,**
334(15) JAMA 1388 (Oct. 21, 2025)

Letters

RESEARCH LETTER

Provision of Abortion Medications Using Online Asynchronous Telemedicine Under Shield Laws in the US

Despite the wave of state-level abortion bans following the overturn of *Roe v Wade*, recent data suggest that abortion rates have remained steady or even increased.[1] One plausible contributor is the rise of online asynchronous telemedicine abortion services—particularly those operating under shield laws, which allow US-licensed clinicians to provide abortion medications to patients in ban states with protection from legal liability.[2] To better understand usage of this care model, we analyzed 15 months of data from Aid Access, a nonprofit asynchronous telemedicine service that provides abortion medications to patients in all 50 states and the District of Columbia. Aid Access leverages shield laws to mail abortion medications to residents in 24 states with near-total or telemedicine bans, operating without the need for such protections in states where telemedicine abortion is legally accessible.[3]

Editorial page 1336

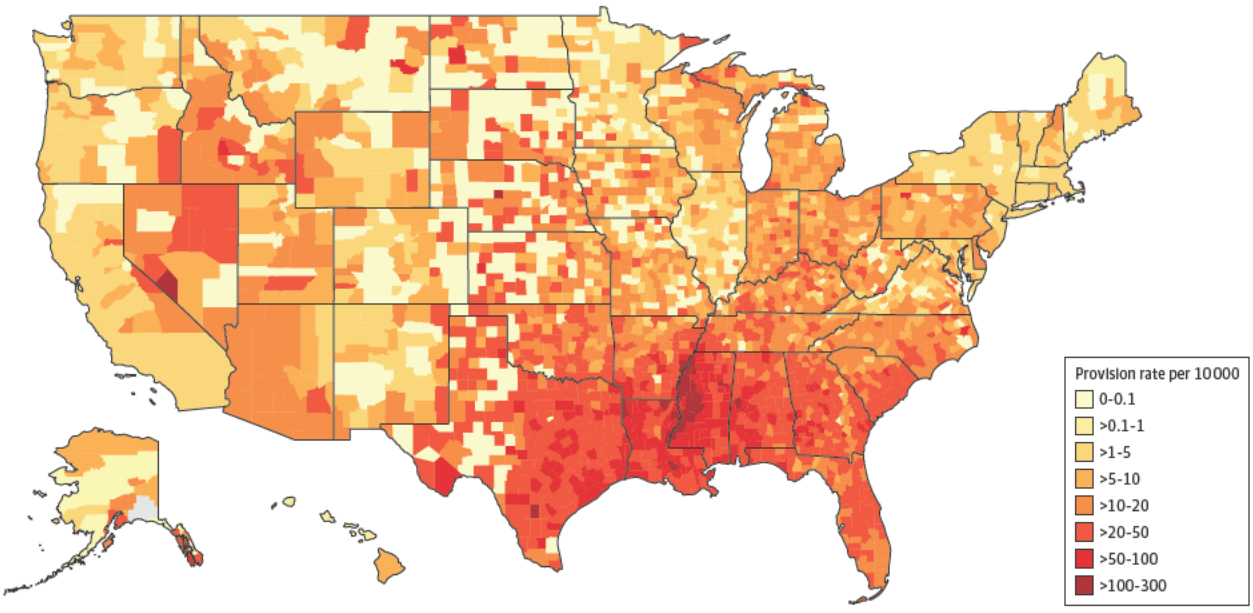
Supplemental content

Methods | During the study period, Aid Access was the only organization serving all states and offering a sliding-scale fee for patients experiencing financial hardship. Patients completed an online consultation reviewed by a US-licensed clinician, and if eligible, were provided with mifepristone and misoprostol, along with instructions and remote support.

We investigated how state abortion policy, travel distance, and poverty were associated with county-level provisions. State policies were classified as protective, telemedicine ban, or near-total ban (eAppendix in Supplement 1). Travel distance was measured from the population centroid of each county to the nearest abortion clinic[4]; poverty was measured as the percentage of residents living below the federal poverty line.[5] We calculated per capita provision rates and unadjusted rate ratios for each of these structural factors. To estimate adjusted rate ratios, we fit a bayesian negative-binomial regression model with fixed effects for policy, travel distance, poverty, and broadband access; state-level random effects; and a population offset. To avoid overadjustment and interpretive ambiguity, we did not include additional aggregate demographic variables. We used R version 4.3.1. All data were fully deidentified. (Patients provided consent for the anonymized use of their data for research purposes at the time of making a request to Aid Access.) The University of Texas at Austin Institutional Review Board approved the study.

Results | Between July 1, 2023, and September 30, 2024, Aid Access provided 118 338 medication abortion pill packs to

Figure. Geographic Variation in Aid Access Provision Rates of Abortion Medication via Telemedicine, July 1, 2023–September 30, 2024



County-level telemedicine abortion provision rates—defined as the number of medication abortion pill packs provided during the study period via online asynchronous telemedicine per 10 000 female residents aged 15 to 44 years—exhibit high geographic variability. The map shows provision rates across counties in the United States and the District of Columbia during the 15-month study period; darker shades indicate higher rates, with the highest concentrations in the South and Midwest, particularly in states with near-total bans.

Table. County-Level Provision Rates and Unadjusted and Adjusted Rate Ratios for Telemedicine Abortion Provision[a]

Variables	Provision rate per 10 000	Rate ratio	
		Unadjusted	Adjusted (95% posterior CrI)
State-level abortion policy			
Protective	5.7	1 [Reference]	1 [Reference]
Telemedicine ban	20.5	3.63	2.33 (1.57-3.38)
Near-total ban	41.3	7.31	3.12 (2.16-4.47)
Travel distance to nearest clinic, miles			
<50	10.1	1 [Reference]	1 [Reference]
50-99	15.9	1.58	1.03 (0.97-1.09)
100-250	25.6	2.53	1.18 (1.10-1.27)
>250	57.7	5.71	1.56 (1.36-1.79)
County residents living in poverty, %			
<5	5.3	1 [Reference]	1 [Reference]
5-9	10.4	1.95	1.47 (1.19-1.81)
10-20	20.3	3.8	1.63 (1.31-2.01)
>20	30.8	5.77	1.94 (1.55-2.42)
County households with ≥10 Mb/s broadband, %			
<60	19.4	1 [Reference]	1 [Reference]
≥60	17.8	0.92	1.19 (1.14-1.26)

Abbreviation: CrI, credible interval.

[a] Provision rates per 10 000 female residents aged 15 to 44 years, unadjusted rate ratios, and adjusted rate ratios were estimated from a negative binomial regression model of county-level telemedicine abortion provision, based on 118 338 abortions provided between July 1, 2023, and September 30, 2024, across 2649 US counties. The regression model includes state abortion policy, travel distance to the nearest clinic, county poverty level, broadband access, and state-level random effects, adjusting for county population via a log offset. Unadjusted rate ratios compare provision rates across categories without adjustment; adjusted rate ratios reflect associations after controlling for the other predictors in the regression model.

residents of 2649 US counties, of which 99 293 (84%) were in states with near-total or telemedicine bans (**Figure**). Unadjusted provision rates were higher in counties with more restrictive state policies, longer travel distances, greater poverty, and lower broadband access (**Table**). However, these structural factors were strongly correlated at the county level. The adjusted rate ratios in the Table reflect the association of each factor with provision rates, holding the other factors constant. After adjustment, provision rates were 3.12 times higher in near-total-ban states (95% posterior credible interval [CrI], 2.16-4.47), and 2.33 times higher in telemedicine-ban states (95% posterior CrI, 1.57-3.38) relative to protective states. Compared with counties within 50 miles of a clinic, provision rates were higher for counties 100 miles to 250 miles (rate ratio, 1.18; 95% posterior CrI, 1.10-1.27) and more than 250 miles (rate ratio, 1.56; 95% posterior CrI, 1.36-1.79) from a clinic. Provision rates also rose with poverty. Compared with counties with less than 5% poverty, counties with 5% to 9% poverty had 1.47 times higher provision rates (95% posterior CrI, 1.19-1.81); those with 10% to 20% poverty, 1.63 times higher provision rates (95% posterior CrI, 1.31-2.01); and those with higher than 20% poverty, 1.94 times higher provision rates (95% posterior CrI, 1.55-2.42). Counties with 60% or higher broadband access had 19% higher provision rates (rate ratio, 1.19; 95% posterior CrI, 1.14-1.26).

Discussion | Asynchronous online telemedicine abortion is widely used in the US. Provision under shield laws is strongly associated with structural barriers to in-clinic care—but even in states where abortion is protected and shield law protections are not required, telemedicine usage remains associated with distance and cost barriers. These findings underscore the public health importance of telemedicine, both as an alternative to the unsafe abortion methods that prevailed under abortion bans before *Roe v Wade*[6] and as a means of reducing access disparities.

Our analysis is limited by reliance on county-level rather than individual-level associations and by data that measure provision of abortion medications rather than completed abortions. Moreover, it does not capture the full scope of telemedicine in states without bans, where other abortion providers also operated during the study period.

Abigail R. A. Aiken, PhD
James G. Scott, PhD
Rebecca Gomperts, PhD

Author Affiliations: LBJ School of Public Affairs, University of Texas at Austin (Aiken); Department of Statistics and Data Sciences and McCombs School of Business, University of Texas at Austin (Scott); Aid Access, Amsterdam, the Netherlands (Gomperts).

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Corresponding Author: Abigail R. A. Aiken, PhD, LBJ School of Public Affairs, University of Texas at Austin, PO Box Y, Austin, TX 78712 (araa2@utexas.edu).

Author Contributions: Dr Aiken had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: All authors.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Aiken.
Critical review of the manuscript for important intellectual content: All authors.
Statistical analysis: Scott.
Obtained funding: Aiken.
Administrative, technical, or material support: Gomperts.

Conflict of Interest Disclosures: Dr Gomperts reported being founder and director of Aid Access. No other disclosures were reported.

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Role of the Funder/Sponsor: The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; or decision to submit the manuscript for publication.

Disclaimer: All authors agree to be accountable for all aspects of the work.

Data Sharing Statement: See Supplement 2.

1. Maddow-Zimet I, Gibson C. Despite bans, number of abortions in the United States increased in 2023. Guttmacher Institute. Published March 2024. Accessed May 18, 2025. https://www.guttmacher.org/2024/03/despite-bans-number-abortions-united-states-increased-2023

2. Cohen DS, Donley G, Rebouché R. Abortion shield laws. *NEJM Evid*. 2023;2(4):EVIDra2200280. doi:10.1056/EVIDra2200280

3. McCann A, Schoenfeld Walker A. Tracking abortion laws across the country. *New York Times*. Updated March 6, 2025. Accessed May 18, 2025. https://www.nytimes.com/interactive/2024/us/abortion-laws-roe-v-wade.html

4. Myers Abortion Facility Database. Updated May 9, 2025. Accessed May 18, 2025. https://osf.io/8DG7R/

5. US Census Bureau. SAIPE state and county estimates for 2021. Accessed May 18, 2025. https://www.census.gov/data/datasets/2021/demo/saipe/2021-state-and-county.html

6. Cates W Jr, Rochat RW. Illegal abortions in the United States: 1972-1974. *Fam Plann Perspect*. 1976;8(2):86-92. doi:10.2307/2133995

CLIMATE CHANGE AND HEALTH

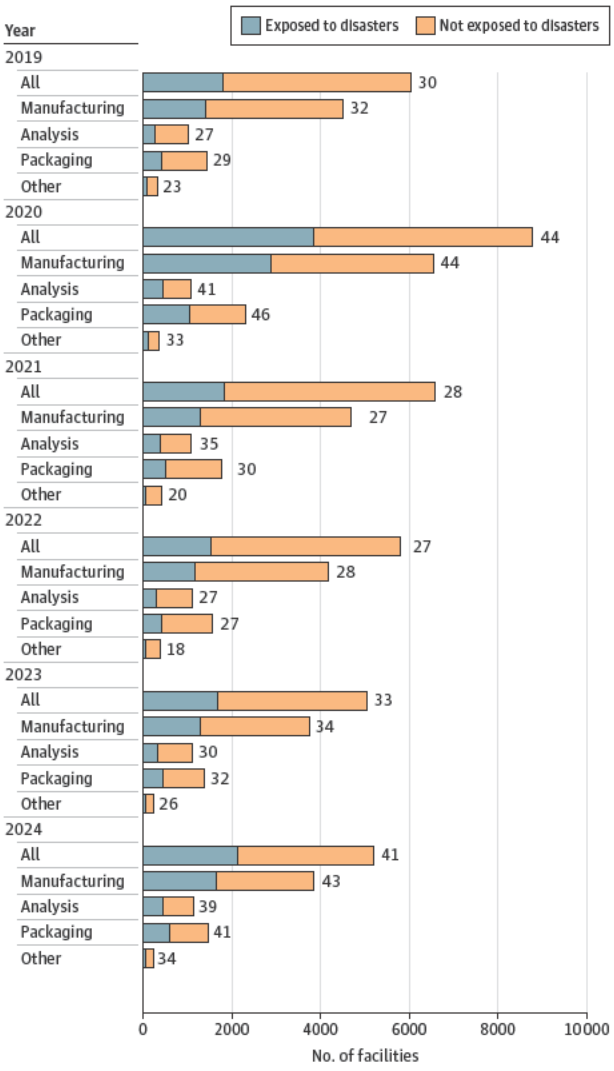
Threats of Weather Disasters for Drug Manufacturing Facilities in the US

In September 2024, Hurricane Helene triggered a nationwide shortage after hitting a Baxter facility in North Carolina that produces 60% of the country's intravenous (IV) fluids.[1] A similar IV shortage was caused when Hurricane Maria hit Puerto Rico in 2017. Climate change–driven extreme weather events impose new threats to established vulnerabilities in the US drug supply.[2] Those threats must be examined to be appropriately mitigated, especially in light of the current administration's recent executive order and policy proposals seeking to increase domestic pharmaceutical production.[3] This study assessed the frequency with which climate-related disaster events affected counties with US drug production facilities.

Supplemental content

Methods | We used archived versions of the US Food and Drug Administration (FDA) Drug Establishments Current Registration Site to identify all US-based drug production facilities that manufacture, prepare, propagate, compound, or process drugs distributed in the US from 2019-2024 (see eMethods in the Supplement). Counties with a Presidential Disaster Declaration from 2019 through 2024 were identified from the Federal Emergency Management Agency (FEMA) disaster declaration database. We included climate-related disaster events: fires, hurricanes, storms, tornadoes, and floods.[4] We calculated the number of facilities that were in counties impacted by disasters, by type of production activity and by type of disaster over time. We used logistic regression to calculate the relative odds of disaster impact, by whether a county had drug production facilities, with year fixed effects and errors clustered at the county level. We followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline, and the Harvard Pilgrim Health Care Institute's institutional review board determined the study to be nonhuman subjects research.

Figure 1. Number and Proportion of Drug Production Facilities in US Counties With at Least One Disaster Declaration



Manufacturing activities include facilities that list manufacture, active pharmaceutical ingredient manufacture, or positron emission tomography drug production in their list of activities. Analysis activities include facilities that analyze raw materials, active pharmaceutical ingredients, inactive ingredients, and the finished drug product. Packaging activities include facilities that pack, repack, or relabel. Other activities include facilities that list transfill, sterilize, particle size reduction, salvage, or distribution as their activities. "Exposed facilities" refers to facilities located in counties with at least one disaster declaration in a given year. Numbers next to the the bars represent percentages of facilities exposed to disasters

Results | There were 10 861 drug production facilities active from 2019 through 2024, ranging from 5063 in 2023 to 8790 in 2020, when 3860 facilities (43.9%) were in counties with at least one disaster declaration. Cumulatively, in the 6-year period, there were 6819 active facilities (62.8%) in counties when a disaster was declared, an average of 2146 active facilities (33.8%) annually over the study period (**Figure 1**). Facilities with all

EXHIBIT 4

Robin Wallace et al, *P040 - Expanding Access to Abortion with Mifepristone and Misoprostol Through 84 Days Estimated Gestational Duration*, 151 Contraception 111117 (Nov. 2025)

Results: Higher perceived abortion stigma predicted greater symptoms of depression, anxiety, and social anxiety. Social support moderated the associations between abortion stigma and symptoms of anxiety and social anxiety. Specifically, such stigma was positively associated with social anxiety symptoms at all levels of partner support (ie, low, moderate, high), but was strongest for those with low partner support. Additionally, perceived abortion stigma was positively associated with symptoms of anxiety and social anxiety for people with moderate and high maternal support (but not low). Abortion disclosure did not moderate the associations between this stigma and mental health symptoms.
Conclusions: This study adds to the emerging literature on perceived abortion stigma and mental health, and findings suggest that the effect of social support on this association may vary based on source.

https://doi.org/10.1016/j.contraception.2025.111116

P040

EXPANDING ACCESS TO ABORTION WITH MIFEPRISTONE AND MISOPROSTOL THROUGH 84 DAYS ESTIMATED GESTATIONAL DURATION

R Wallace
Planned Parenthood Federation of America, New York, NY, US
S Diemert, O Ades-Lawlor, R Topp, H Simons

Objectives: We aimed to assess efficacy and safety of a combined medication abortion regimen, using mifepristone and repeat buccal misoprostol dosing, for patients seeking abortion at 78-84 days estimated gestational duration in an outpatient setting in the US.
Methods: We are conducting a secondary analysis of data from 14 US-based Planned Parenthood affiliates that provided medication abortion for eligible patients with an estimated gestational duration of 78-84 days from April 2024 to December 2024, with additional data through March 2025 expected. Affiliates reported the total number of patients receiving medication abortion at this gestational duration (n = 711) and available outcome data. Among medication abortions with known outcomes (n = 217), we will calculate the incidence rates and 95% confidence intervals for completed abortion, ongoing pregnancy, subsequent procedure, and emergency department or hospital visits associated with medication abortion.
Results: Out of 217 known outcomes of the 711 total medication abortions provided at 78-84 days estimated gestational duration, preliminary raw data includes 27 ongoing pregnancies, 22 aspirations performed for ongoing pregnancies, 10 aspirations performed for other reasons, and 21 visits to an emergency department or hospital.
Conclusions: Use of medication abortion at 78-84 days estimated gestational duration in our study's US-based outpatient health centers resulted in similarly low ongoing pregnancy and need for aspiration as shown by prior research conducted in international inpatient settings. Offering medication abortion with a combined regimen, including mifepristone followed 24-48 hours later by buccal misoprostol every four hours for 2-3 doses, may increase access to safe, effective abortion beyond 77 days of pregnancy.

https://doi.org/10.1016/j.contraception.2025.111117

P042

THE ROLE OF ABORTION RESTRICTIONS IN COUNSELING AT FETAL CARE CENTERS

V Manthena
University of Chicago, Chicago, IL, US
P Gopal, A Akhter, JT Fry, JL Muñoz, J Chor, AF Shaaban, A Premkumar

Objectives: Fetal care centers (FCCs) or hospital-based institutions focused on the diagnosis and management of congenital anomalies have increased over the past decade, but little is known about their abortion care practices including eliciting interest, counseling, and referrals, or how these practices are influenced by institutional or state policies on abortion care.
Methods: We conducted a cross-sectional study across US North American Fetal Therapy Network (NAFTNet) sites, including FCCs in states or institutions with restrictive and permissive abortion policies, as defined by the Guttmacher Institute. Providers were recruited via snowball sampling, and surveys were distributed electronically through REDCap. Semi-structured key interviews were performed among a subgroup of NAFTnet site representatives. Interviews were audio-recorded, transcribed and analyzed using grounded theory, with quantitative data summarized statistically.
Results: Twenty-three providers (3 pediatric surgeons, 20 maternal-fetal medicine (MFM) subspecialists) completed the survey, and 12 providers (1 pediatric surgeon, 11 MFMs) expressed interest in the interview. Among those interviewed, the majority were female (58.3%) and worked at FCCs located in settings with restrictive or partly permissive abortion policies (58.3%). Key themes from interviews by providers located in permissive settings included ease and comfort in abortion counseling, while providers located in hospital systems or states with restrictive abortion policies emphasized counseling practices based on institutional or state restrictions and conscientious provision.
Conclusions: Providers working at FCCs face unique issues in eliciting interest in and counseling about abortion care, which diverge based on institutional and state restrictions. Future research should investigate patient experiences of abortion care after consultation at an FCC.

https://doi.org/10.1016/j.contraception.2025.111118

P043

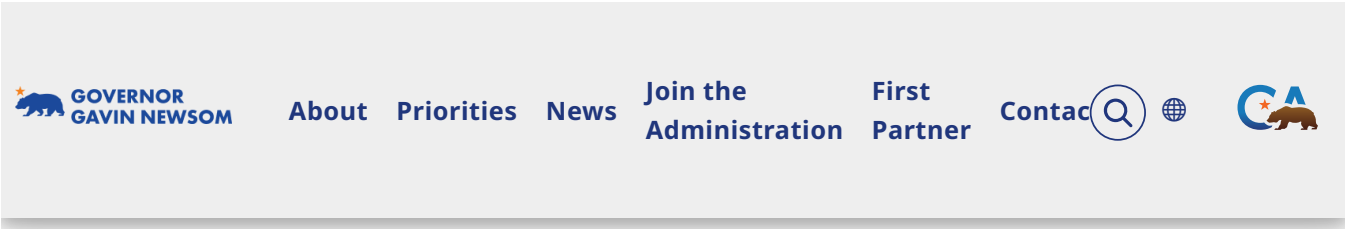
TRENDS IN MISOPROSTOL PRESCRIBING AND DISPENSING ACROSS NORTH CAROLINA PHARMACIES

L Joudeh
University of North Carolina at Chapel Hill, Chapel Hill, NC, US
C Muir, V Miller, A Schultz

Objectives: The aim of this study is to assess misoprostol dispensing practices across North Carolina pharmacies. We sought to identify trends in misoprostol dispensing in low access healthcare counties, rural counties, and by pharmacy type.
Methods: We used a secret-shopper approach to assess whether pharmacies dispense misoprostol. The secret-shopper called in the role of clinic staff. Chi-squared tests and Fisher's exact tests were used for statistical analysis.
Results: Of the 100 counties in North Carolina, 94 (94%) counties were contacted. Ninety-nine (99%) counties had a chain pharmacy represented and 95 (95%) had an independent pharmacy represented. Some 173 (77.6%) pharmacies dispensed misoprostol, 12 (5.4%) had conditional dispensing practices, and 38 (17.0%) did not

EXHIBIT 5

Governor Newsom Signs New Landmark Laws to Protect Reproductive Freedom, Patient Privacy Amid Trump's War on Women,
Gov. Gavin Newsom (Sep. 26, 2025)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Sep 26, 2025

Governor Newsom signs new landmark laws to protect reproductive freedom, patient privacy amid Trump's war on women

What you need to know: Governor Newsom signed a series of bills, including AB 260 and AB 1525, to safeguard access to reproductive health care.

SACRAMENTO – In a significant effort to advance reproductive freedom, Governor Gavin Newsom today signed legislation to protect access to essential reproductive care and help shield health care providers, patients, and lawyers from adverse legal action.

Governor Newsom signed AB 260 (Cecilia Aguiar-Curry), offering health care providers the option to prescribe abortion care medication to patients anonymously, ensuring California-regulated health plans cover mifepristone regardless of FDA approval status, and strengthening protections for health care providers from criminal prosecution and other legal action for administering medication abortion drugs.

The Governor also signed AB 1525 (Committee on Judiciary), helping to shield attorneys assisting other states with access to reproductive care from State Bar discipline.

> *"California stands for a woman's right to choose. I'm proud to sign these bills to protect access to essential health care and shield patients and health care providers in the face of amplified attacks on the fundamental right to reproductive freedom."*
>
> Governor Gavin Newsom

"With the Governor's signature on AB 260, California will continue to be a national leader in protecting reproductive and privacy rights," **said Assembly Majority Leader and Legislative Women's Caucus Chair Cecilia Aguiar-Curry.** "I appreciate the partnership with the Administration as we fight for the sanctity of the patient-health professional relationship, and the safety of Californians and their health providers."

"Today, even in California, access to abortion and

reproductive health care hangs in the balance. President Trump's Administration and Republican members of Congress continue to attack reproductive health care access on all fronts, including ongoing threats to medication abortion and already successfully defunding all 109 Planned Parenthood health centers in California. And we know they won't stop there," **said Planned Parenthood Affiliates of California CEO and President Jodi Hicks.** "As Planned Parenthood fights to keep health centers open to provide the reproductive health care so many Californians rely on, Planned Parenthood Affiliates of California is grateful to the Governor for signing Assemblymember Aguiar-Curry's bill, AB 260. This significant policy will help safeguard access to medication abortion for many Californians and protect the ability of our state's abortion providers to continue providing this life-saving care."

Other bills the governor signed today include:

- **Assembly Bill 45** by Rebecca Bauer-Kahan (D-Orinda) – Privacy: health data: location and research.
- **Assembly Bill 50** by Mia Bonta (D-Oakland) – Pharmacists: furnishing contraceptives.

California's actions to protect reproductive freedoms

In the years since the Supreme Court's Dobbs v. Jackson decision, California has stepped up consistently to protect reproductive freedom, including:

- June 2025: The 25-26 budget expanded the authority of CalRx to purchase brand-name drugs. This change gives the state more tools to respond to supply chain disruptions, market manipulation, or politically motivated restrictions that could

threaten access to essential medications — including medication used for abortion care.

- May 2024: Governor Newsom signed SB 233 with the Legislative Women's Caucus, allowing Arizona abortion providers to temporarily provide abortion care to patients from Arizona who travel to California for care following the Arizona Supreme Court's ruling to reimpose a regressive 1864 law imposing a near-total abortion ban in their state.
- January 2024: The Reproductive Freedom Alliance, led by Governor Newsom, **filed an amicus curiae brief** with the U.S. Supreme Court in the case of Food and Drug Administration, et al., v. Alliance for Hippocratic Medicine, arguing that, if the Court allowed the Fifth Circuit's decision rejecting FDA's approval of mifepristone to stand, it would undermine Governors' ability to provide adequate healthcare services and would have far-reaching implications beyond reproductive healthcare. The Supreme Court sided with the FDA in June 2024.
- April 2023: Governor Newsom procured an **emergency stockpile of Misoprostol,** a **safe and effective medication abortion** drug, as legal challenges continue to move through the courts in an attempt to block abortion medication.
- March 2023: Governor Newsom joined 13 other Governors in calling on **major pharmacies to clarify plans for** dispensing Mifepristone and other actions they plan to take to safeguard access to reproductive health care drugs.
- February 2023: Governor Newsom launched the **Reproductive Freedom Alliance**, a coalition of 23 Governors fighting together to protect and advance reproductive freedom.
- November 2022: Voters pass Governor Newsom

and the Legislature's **Proposition 1**, an amendment to the state constitution to enshrine the right to reproductive freedom – including abortion care and contraception.

- September 2022:
  - Governor Newsom **launched Abortion.CA.Gov** to ensure people across California, and the country, can access essential information regarding reproductive health care, including resources available to support access to care.
  - Governor Newsom, working with the Legislature, ensured California passed **the largest reproductive freedom bill package** in state history, building firewalls around California as a reproductive freedom state.

- June 2022:
  - Governor Newsom signed legislation to help **protect patients and providers** in California against radical attempts by other states to extend their anti-abortion laws into California, on the same day Roe v. Wade was overturned.
  - California invested over **$200 million in reproductive health care**.
  - Issued an **Executive Order** protecting state-held data and information from being used by out-of-state anti-abortion entities to target providers and patients.
  - Joined the Governors of Oregon and Washington to **launch a new Multi-State Commitment** to defend access to reproductive health care and protect patients and providers.

Categories: Health care, Press releases, Recent news

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EXHIBIT 6

US FDA Has Delayed Abortion Pill Safety Study,
Bloomberg News Reports,
Reuters (Dec. 8, 2025, at 14:23 PT)

US FDA has delayed abortion pill safety study, Bloomberg News reports

By **Reuters**

December 8, 2025 2:23 PM PST · Updated December 8, 2025

Signage is seen outside of the Food and Drug Administration (FDA) headquarters in White Oak, Maryland, U.S., August 29, 2020. REUTERS/Andrew Kelly/File Photo Purchase Licensing Rights

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U.S. Food and Drug Administration

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Dec 8 (Reuters) - The U.S. Food and Drug Administration has delayed a review of safety data for the abortion drug mifepristone at Commissioner Marty Makary's request, Bloomberg News reported on Monday, citing people familiar with the matter.

Makary has told agency officials to delay the safety review until after the midterm elections, the report said.

"The FDA's comprehensive scientific reviews take the time necessary to get the science right and that's what Dr. Makary is ensuring," Department of Health and Human Services spokesperson Andrew Nixon said.

U.S. Health Secretary Robert F. Kennedy Jr. had said earlier this year that the review of mifepristone is ongoing.

Mifepristone is the first pill, followed by the drug misoprostol, for medication abortion in the first 10 weeks of pregnancy, and won FDA approval in 2000.

Reporting by Mariam Sunny and Sahil Pandey in Bengaluru; Editing by Maju Samuel

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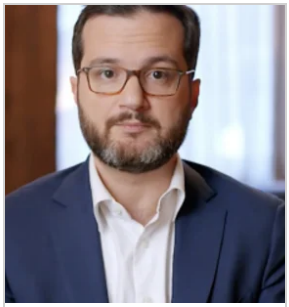

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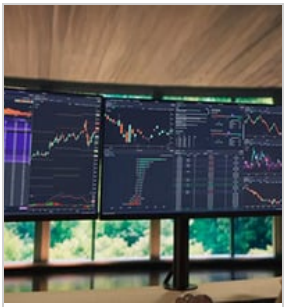

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SpaceX insider share sale sets $800 billion valuation amid possible IPO, letter shows

Business · December 12, 2025 · 9:17 PM PST · 17 mins ago

SpaceX is preparing to go public next year and has opened a secondary share sale that would value the company at $800 billion, according to a letter to shareholders sent by the company's CFO Bret Johnsen and reviewed by Reuters.

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EXHIBIT 7

Elizabeth Troutman Mitchell, *EXCLUSIVE: Makary Responds to Report Saying He Slow-Walked Abortion Pill Safety Review*, Daily Signal (Dec. 9, 2025)

HEALTH CARE NEWS

EXCLUSIVE: Makary Responds to Report Saying He Slow-Walked Abortion Pill Safety Review

Elizabeth Troutman Mitchell December 09, 2025

Elizabeth Troutman Mitchell @TheElizMitchell

Elizabeth Troutman Mitchell is the White House Correspondent for "The Daily Signal." Send her an email.

FIRST ON THE DAILY SIGNAL—Food and Drug Administration Commissioner Dr. Marty Makary said the review of the abortion drug mifepristone is in the “data acquisition phase” following a report saying he is delaying the process.

“We do an ongoing review, but we’re also engaging in a robust study that can serve to validate or not validate other numbers that have been put out there in the literature,” he told The Daily Signal in an exclusive interview.

Makary and Secretary of Health and Human Services Robert F. Kennedy Jr. have pledged to do a review of the safety of abortion drugs following a study from the

Ethics and Public Policy Center, which showed 11% of women experience adverse effects after taking the pill regimen. Bloomberg reported that Makary is slow-walking the review, prompting calls from leading pro-life groups for him to be removed from his post.

Makary said he is personally responsible for the review.

”Ultimately, I’m responsible, and so this analysis is going to be done under my auspices, and it’ll be reported up to me,” he said, “and I’m going to be involved.”

The FDA is currently in the “data acquisition phase” of the abortion pill review.

“Appropriately, many members of Congress have said, ‘Hey, this is a good time to check in and do a robust study.’ So, part of a robust study is data acquisition,” he said. “And so, we’re in that data acquisition phase to get the right data to be able to do this study.”

Makary said he is unable to predict the “results or the timeframe” of the review.

“The shutdown was a little bit of a setback in that, but we’re gonna do it and whenever the results are available,” he said, “we’re gonna make them public.”

He laid out the plan for the review. Once the data has finished coming in, the FDA will review it and ensure there are no missing data fields that change the way the analysis is designed.

“If there are, then you change the design of the study and you account for how the landscape of the data actually is and the way it presents,” he said. “And then you look at the preliminary exploratory results, and then you change the analysis to account for confounding variables.”

Next, the FDA will “repeat and validate.”

“These are all routine steps in robust data analysis,” he said. “Studies are often repeated, done by multiple reviewers or statisticians. So, we’re going to do it the right way. And look, I know there are a lot of voices in this space, but I’m committed to doing this the right way.”

The former Johns Hopkins professor blamed the rumor mill for Bloomberg’s story saying he has slow-walked the mifepristone review.

“There’s a lot of rumors that are circulating out there,” he said. “We live in a very partisan time, and so you’re going to see the echo chambers of social media sort of magnify rumors, things that are just not true. There has been an ongoing review of mifepristone.”

The Risk Evaluation & Mitigation Strategies, or REMS, policy already requires the FDA to perform an ongoing review of medication, Makary said.

“There’s always an ongoing review of that medication, and we need to be open to the fact that maybe there’s a new drug interaction that was not appreciated,” he said.

Makary said it’s possible “there’s a complication that was not recognized previously” with the abortion pill. What the FDA finds in the study will join the “broader discussion nationally,” he said.

“We’re not going to decide what the results are before we’ve done the study,” he said. “We’re doing the study the right way. And when you do the study the right way, and I’ve done dozens of these studies as a Johns Hopkins professor, you gotta do the studies in data the right way with the right pace.”

The Ethics & Public Police Center study found that about 11% of women experience sepsis, infection, hemorrhaging, or another serious adverse event within 45 days following a mifepristone abortion. This has led to calls to reinstate the in-person dispensing requirement for mifepristone.

In April 2021, the Biden administration’s FDA stopped requiring that abortion drugs be dispensed to women in person, which allowed women to receive them through telehealth appointments and by mail. The FDA has not enforced the in-person dispensing requirement ever since.

Seven out of 10 American voters say they don’t think it’s safe for abortion drugs to be sent via mail, according to a McLaughlin & Associates poll.

When asked by The Daily Signal if it’s safe for women to take the abortion pill at home without seeing a doctor first, Makary said the Ethics & Public Police Center study “was done in claims data, so it didn’t have granularity into the patient characteristics in a way that many researchers would want to have.”

“Tha reasons why we are doing a bigger, more robust study,” he said.

EPPC abortion pill study authors, Ryan T. Anderson and Jamie Bryan Hall, responded that the study they conducted was "the biggest and most robust study conducted thus far—much more so than the studies the FDA has previously relied on—and we are confident that the FDA will find similar results to ours using real-world data."

"However, the FDA need not complete that study to reinstate the in-person doctor visit. We already have seen women coercively poisoned by boyfriends to kill their unborn babies," they told The Daily Signal. "This couldn't happen if the FDA once again required in-person doctor visits as they did during the first Trump administration."

The FDA approved a second generic version of the abortion pill on Oct. 2, shortly before the government shutdown, another move that sparked pro-life backlash. Makary said the FDA had to approve the drug or get sued.

"There's a law that requires the FDA to approve a molecule if it's similar to a branded molecule, so we had no discretion," Makary told The Daily Signal. "If we chose to look at that application and say, no, we're not going to approve this, we'd 100% get sued, and we'd 100% lose."

"It would all happen very quickly because the law is very clear now with drugs that we approve as new branded drugs," he said. "It's a very different law. So we have discretion to weigh risks and benefits. But when it comes to generic compounds, the law is pretty clear."

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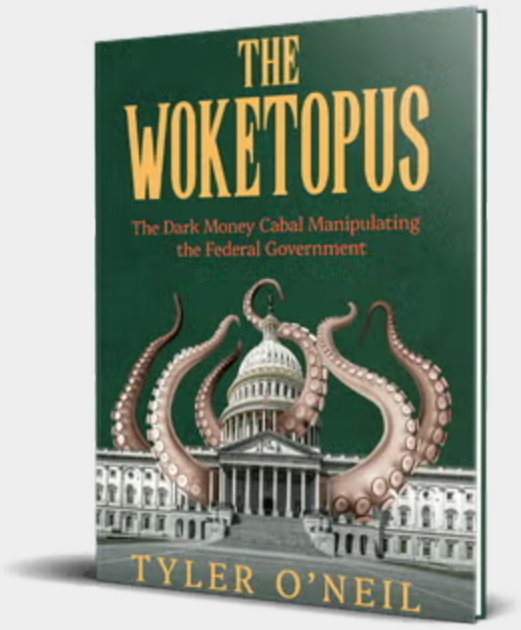

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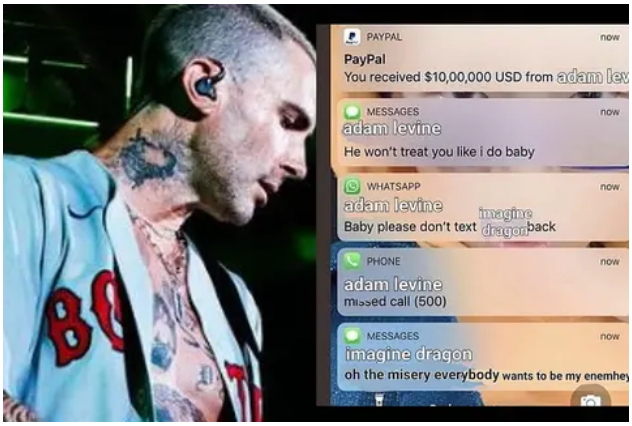

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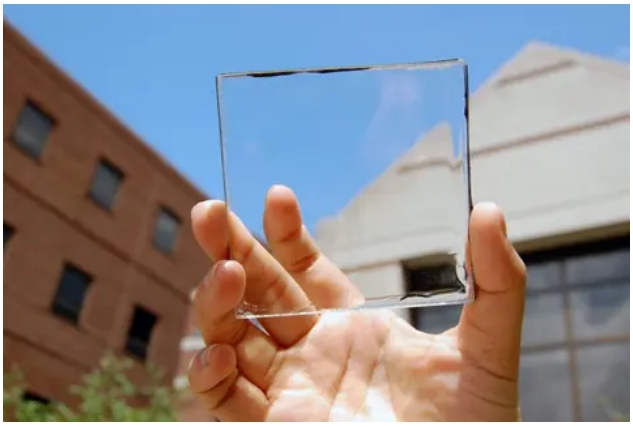

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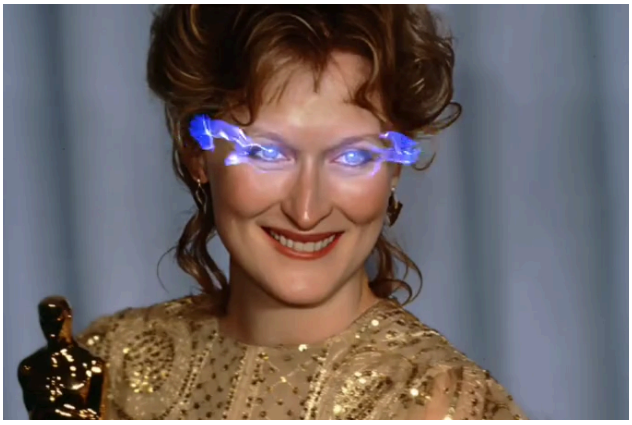

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EXHIBIT 8

Ian Lopez, *RFK Jr. Says Biden 'Twisted the Data' on Abortion Pill Safety*, BL (Sep. 4, 2025, at 12:45 ET)

RFK Jr. Says Biden 'Twisted the Data' on Abortion Pill Safety

Sept. 4, 2025, 12:45 PM EDT

US Health Secretary Robert F. Kennedy Jr. is accusing the Biden administration of having "twisted the data" on safety of the abortion drug mifepristone.

The Department of Health and Human Services chief told lawmakers at a Senate Finance Committee hearing Thursday that the Trump administration is committed to reviewing mifepristone safety and keeping politics out of his approach.

In May, Kennedy ordered Food and Drug Administration Commissioner Marty Makary to review mifepristone, prompting a request by Sen. James Lankford (R-Okla.) at Thursday's hearing for an update on the timing for the review.

Kennedy said he couldn't provide an exact timeline, though noted he spoke with Makary on Wednesday and that the HHS is frequently getting new data on the drug to review.

"We're getting data in all the time, new data on that, we're reviewing," Kennedy said. "We know that during the Biden administration, they actually twisted the data, to bury one of the safety signals, a very high safety signal, around 11%, so we're going to make sure that that doesn't happen anymore."

The safety of the drug has been a key focus of Republicans' anti-abortion efforts. A recent study from conservative think tank the Ethics & Public Policy Center claimed health data it reviewed on the medication warrants fresh FDA review of the drug.

The EPPC study drew quick pushback form public health policy experts who took issue with its methodology and described it as part of a broader effort to block access to medication abortion. The EPPC, however, billed the study as the "largest-known" on the drug, claiming it found that one in 10 users had a significant adverse health event.

Following up on the topic Thursday, Sen. Steve Daines (R-Mont.) pushed Kennedy as to whether the HHS plans to replicate other research critical of medication abortion. Kennedy, however, couldn't provide specifics, though noted that Makary said the topic was pressing.

Daines also asked about whether Kennedy would repeal Covid-era changes easing mifepristone restrictions that made the drug accessible via telemedicine. Kennedy, however, said he wasn't sure whether the White House had taken a position on that issue, and that he'd have to get back to Daines.

Republican lawmakers are taking increasingly aggressive approaches against mifepristone. On Wednesday, the Texas state legislature approved a bill that will allow any Texan to sue an abortion pill manufacturer or distributor.

The Senate Finance hearing focused on the HHS' shifting approach on vaccines under Kennedy's leadership, following his overhaul of the Centers for Disease Control and Prevention.

The attacks were largely from Democratic senators, though Republican Bill Cassidy (La.)—whose vote was crucial in securing Kennedy's confirmation as HHS secretary—took a critical tone with Kennedy.

Sen. Thom Tillis (R-N.C.) also took issue with Kennedy's commentary on Project Warp Speed, handling of HHS science, and the White House's firing of Susan Monarez from her role as CDC director.

To contact the reporter on this story: Ian Lopez in Washington at ilopez@bloomberglaw.com

To contact the editors responsible for this story: Zachary Sherwood at zsherwood@bloombergindustry.com; Brent Bierman at bbierman@bloomberglaw.com

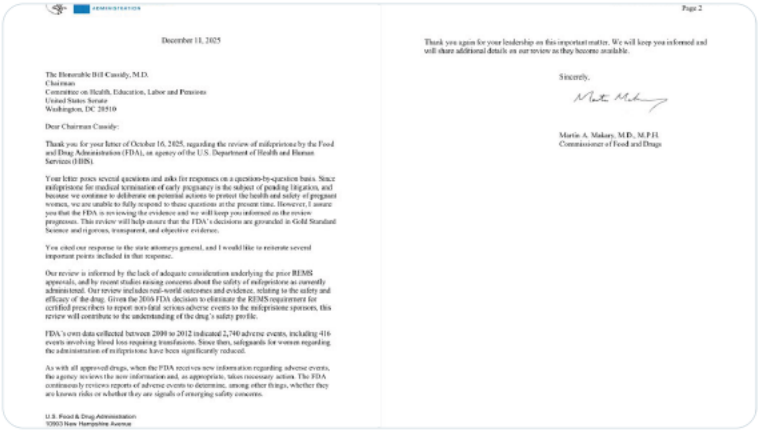
EXHIBIT 9

U.S. Senator Bill Cassidy, M.D. (@SenBillCassidy), X (Dec. 12, 2025, at 13:05 PT)

Post

U.S. Senator Bill Cassidy, M.D.
@SenBillCassidy

As chair of the HELP Committee and a strong pro-life conservative, FDA's response to Congress is unacceptable. Republicans have been pressing FDA to provide answers on the status of its promised safety study of the chemical abortion drug and information about the second generic's approval. The American people deserve to know why HHS and FDA continue to ignore their responsibility to safeguard mothers and unborn children from this harmful drug.



December 11, 2025

The Honorable Bill Cassidy, M.D.
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Dear Chairman Cassidy:

Thank you for your letter of October 16, 2025, regarding the review of mifepristone by the Food and Drug Administration (FDA), an agency of the U.S. Department of Health and Human Services (HHS).

Your letter poses several questions and asks for responses on a question-by-question basis. Since mifepristone for medical termination of early pregnancy is the subject of pending litigation, and because we continue to deliberate on potential actions to protect the health and safety of pregnant women, we are unable to fully respond to these questions at the present time. However, I assure you that the FDA is reviewing the evidence and we will keep you informed as the review progresses. This review will help ensure that the FDA's decisions are grounded in Gold Standard Science and rigorous, transparent, and objective evidence.

You cited our response to the state attorneys general, and I would like to reiterate several important points included in that response.

Our review is informed by the lack of adequate consideration underlying the prior REMS approvals, and by recent studies raising concerns about the safety of mifepristone as currently administered. Our review includes real-world outcomes and evidence, relating to the safety and efficacy of the drug. Given the 2016 FDA decision to eliminate the REMS requirement for certified prescribers to report non-fatal serious adverse events to the mifepristone sponsors, this review will contribute to the understanding of the drug's safety profile.

FDA's own data collected between 2000 to 2012 indicated 2,740 adverse events, including 416 events involving blood loss requiring transfusions. Since then, safeguards for women regarding the administration of mifepristone have been significantly reduced.

As with all approved drugs, when the FDA receives new information regarding adverse events, the agency reviews the new information and, as appropriate, takes necessary action. The FDA continuously reviews reports of adverse events to determine, among other things, whether they are known risks or whether they are signals of emerging safety concerns.

U.S. Food & Drug Administration
10903 New Hampshire Avenue

Page 2

Thank you again for your leadership on this important matter. We will keep you informed and will share additional details on our review as they become available.

Sincerely,

Martin A. Makary, M.D., M.P.H.
Commissioner of Food and Drugs

:05 PM · Dec 12, 2025 · **17.5K** Views

46 34 57 7

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EXHIBIT 10

Video posted by Elizabeth Mitchell Troutman (@TheElizMitchell), X, at 02:02–2:19 (Dec. 9, 2025, at 14:56 PT)

Post

Elizabeth Troutman Mitchell
@TheElizMitchell

EXCLUSIVE ‼️: @DrMakaryFDA responded to a report saying he is delaying the review of the abortion pill.

The FDA is currently in the “data acquisition phase” of the review," he told @DailySignal.

“We do an ongoing review, but we’re also engaging in a robust study that can serve to validate or not validate other numbers that have been put out there in the literature."

"Ultimately, I’m responsible, and so this analysis is going to be done under my auspices, and it’ll be reported up to me," he said.

Makary said he is unable to predict the “results or the timeframe” of the review, and the shutdown was a "setback."

It’s possible “there’s a complication that was not recognized previously” with the abortion pill, he said.

2:56 PM · Dec 9, 2025 · **34.8K** Views

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EXHIBIT 11

T. Elliot Gaiser et al., *The Truth of Erasure: Universal Remedies for Universal Agency Actions*, U. Chi. L. Rev. Online (Aug. 28, 2024)

08/28/24 U. Chi. L. Rev. Online *1

The Truth of Erasure: Universal Remedies for Universal Agency Actions

T. Elliot Gaiser, Mathura Sridharan, & Nicholas Cordova[*]

* * *

Introduction

Courts, litigants, and scholars should not be confused by the ongoing debate about nationwide or so-called "universal" injunctions: the proper scope of remedies under the Administrative Procedure Act (APA) and other statutes providing for judicial review of agency action is "erasure." This Article aims to save scholars' recent progress in showing the legality of stays and vacatur under the APA from muddled thinking that conflates these forms of relief with other universal remedies that face growing criticism.

Begin with first principles. When a federal court reviews a legislative enactment that conflicts with a source of higher law (i.e., the Constitution), the court engages in what is essentially a choice-of-law analysis: the court chooses to apply the higher law to the parties in the case at hand and declines to apply the conflicting lower law to those parties. It does not "strike down" the lower law or repeal it, any more than a court choosing to apply Ohio law rather than Michigan law to a tort suit "strikes down" the unchosen Michigan law. To "strike down" the statute in this way would be to exercise legislative, not judicial

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[*] T. Elliot Gaiser is the Solicitor General of Ohio. He previously clerked for Associate Justice Samuel A. Alito, Jr., at the Supreme Court of the United States; for Judge Neomi Rao on the U.S. Court of Appeals for the D.C. Circuit; and for Judge Edith H. Jones on the U.S. Court of Appeals for the Fifth Circuit. He holds a J.D. from The University of Chicago Law School and a B.A. in Political Economy and Rhetoric & Public Address from Hillsdale College.

Mathura J. Sridharan is the Director of Ohio's Tenth Amendment Center and serves as a Deputy Solicitor General in the Ohio Attorney General's Office. She previously clerked for Judge Steven J. Menashi on the U.S. Court of Appeals for the Second Circuit and Judge Deborah A. Batts on the U.S. District Court for the Southern District of New York. She holds a J.D. from New York University School of Law, and an M.Eng. in Electrical Engineering & Computer Science and a B.S. in Electrical Engineering & Computer Science and Economics from Massachusetts Institute of Technology.

Nicholas A. Cordova is an associate at Boyden Gray PLLC and former Simon Karas Fellow to the Ohio Solicitor General. He previously clerked for Judge Paul B. Matey on the U.S. Court of Appeals for the Third Circuit. He holds a J.D. from Harvard Law School and a B.A. in Political Science from Waynesburg University.

power—and courts may only exercise the latter. Once the right law has been identified, the remedy is to apply that law to the parties in the case. Nationwide or "universal" injunctions that intend to deliberately affect parties beyond the case exceed the judiciary's equitable powers, and perhaps the judicial power altogether. But the increasing frequency of such overbroad remedies flows from the fallacy that a court, in finding that the legislative enactment must yield to a higher law in a given controversy, has "erased" the statute. Correct the fallacy, and the proper scope of the remedy comes into focus.

But the "erasure" conception of judicial review is not a fallacy in the context of federal agency action. Federal agency action is subject to review under statutes like the APA that authorize courts to "set aside," "postpone the effective date of," "reverse," or grant other relief directed at agency action itself, rather than at the officials responsible for carrying out agency action. These statutes reflect the principle that Article III courts review agency action analogously to decisions by Article I courts. Federal courts can thus review agency action much like a bankruptcy court's judgments or a magistrate judge's report and recommendations. This power to invalidate unlawful agency action exists in other places as well. For example, courts are also allowed to invalidate unlawful agency action taken under the Clean Air Act and the Securities Exchange Act of 1934. This Article's arguments defending universal remedies under the APA apply equally to agency action reviewed under these provisions.

Professor Mila Sohoni and others have shown that Congress designed judicial review of agency action under the APA to replicate the appellate review model, whereby a superior court judgment takes as its object the inferior court's judgment and invalidates that initial judgment if it is unlawful. Agency action reviewed under the APA and similar statutes essentially stands as an inferior-court judgment, subject to vacatur if the reviewing court finds it unlawful. This view is consistent with that of lawyer and academic Jonathan Mitchell, whose extensive work criticizing universal injunctions expressly carves out review of agency action. Congress's decision to subject agency action to these broad remedies is the result of its post–New Deal understanding that agency rulemaking is an exercise of nationwide quasi-judicial, quasi-legislative power that must be checked by judicial review of matching scope. Thus, stay and vacatur of agency action in these contexts are presumptively lawful and appropriate remedies, whereas universal injunctions of presidential action and universal injunctions against enforcement of statutes are not.

Part I of this Article surveys scholarship that shows that the APA authorizes federal courts to issue relief that undoes the agency action

under review. That work has established that vacatur is ordinarily the appropriate remedy for an agency rule found to be unlawful. Part II draws on that work to explain that the APA similarly authorizes universal *preliminary* relief from agency action. Part III shows why the Constitution not only permits, but requires, unlawful agency action to be subject to vacatur. Part IV applies the preceding discussion to contemporary debates about other forms of universal relief. This article aims to keep these debates from overspilling their proper doctrinal banks and disfiguring judicial review of federal agency action, where universal remedies should remain the norm as Congress intended.

I. The APA Instructs Courts to Invalidate Unlawful Agency Action

Scholars have demonstrated that courts truly "strike down" or "erase" unlawful agency action reviewed under the APA. Moreover, in both a recent stay grant and concurrence, Justice Brett Kavanaugh recognized that this distinguishes judicial review of agency action from judicial review of statutes, where universal injunctions are increasingly (and appropriately) suspect. And judicial practice wholeheartedly agrees that whatever may be said of universal injunctions involving statutes, courts should issue universal remedies for unlawful agency action. Every circuit has effectively recognized that the APA authorizes it to vacate a rule,[1] and the D.C. Circuit often does so "five times before breakfast." Because scholarship and practice firmly establish vacatur of federal agency action, this Part only summarizes the primary reasons—textual and historical—that others have advanced in support of it.

[1] *E.g.*, Harmon v. Thornburgh, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989); Nat'l Org. of Veterans' Advocs., Inc. v. Sec'y of Veterans Affs., 48 F.4th 1307, 1317 (Fed. Cir. 2022); N.H. Hosp. Ass'n v. Azar, 887 F.3d 62, 77 (1st Cir. 2018); Nat'l Black Media Coal. v. FCC, 791 F.2d 1016, 1020, 1024 (2d Cir. 1986); Prometheus Radio Project v. FCC, 652 F.3d 431, 453–54, 453 n.25 (3d Cir. 2011); N.C. Growers' Ass'n v. United Farm Workers, 702 F.3d 755, 759 (4th Cir. 2012); Chamber of Com. of the U.S. v. Dep't of Labor, 885 F.3d 360, 363 (5th Cir. 2018); Mason Gen. Hosp. v. Sec'y of Dep't of Health & Hum. Servs., 809 F.2d 1220, 1231 (6th Cir. 1987); H & H Tire Co. v. Dep't of Transp., 471 F.2d 350, 355–56 (7th Cir. 1972); Menorah Med. Ctr. v. Heckler, 768 F.2d 292, 297 (8th Cir. 1985); Nat. Res. Def. Council v. U.S. EPA, 526 F.3d 591, 594 (9th Cir. 2008); Zen Magnets, LLC v. Consumer Prod. Safety Comm'n, 841 F.3d 1141, 1155 (10th Cir. 2016); Alabama v. Ctrs. for Medicare & Medicaid Servs., 674 F.3d 1241, 1244 (11th Cir. 2012).

A. History Supports Continued Use of Vacatur

Reviewing the APA's history sets the stage for analyzing its text. Section 706 of the APA directs that "the reviewing court shall . . . hold unlawful and set aside agency action" that is "found to be" unlawful. When Congress was debating and drafting the APA, both Congress and the Executive Branch understood that the phrase "set aside" prescribed judicial invalidation of unlawful regulation. Just four years before the APA's enactment, the Emergency Price Control Act of 1942 gave an Emergency Court of Appeals exclusive jurisdiction "to stay, restrain, enjoin, or set aside, in whole or in part, any provision of th[e] Act . . . or any provision of any such regulation [authorized by the Act] . . . or to restrain or enjoin the enforcement of any such provision." This statute shows that Congress understood "set aside" to be an action against an entire provision of a statute or regulation, and distinct from an order "to restrain or enjoin" a provision's "enforcement" against plaintiffs to a lawsuit. Congress recognized these as different remedies and authorized both in the Emergency Price Control Act. Accordingly, Congress knowingly authorized the greater "set aside" remedy in Section 706 of the APA.

The Executive Branch shared this understanding that to "set aside" agency action meant to invalidate it wholly. The 1941 Attorney General's Report on Administrative Procedure, in discussing judicial review of agencies' formal rulemaking, explained that a "judgment adverse to a regulation results in setting it aside." That sentence shows then-Attorney General Robert H. Jackson's understanding that the object of the reviewing court's judgment is the regulation itself, not the regulation's application in the case at hand.

President Franklin D. Roosevelt used the term "set aside" to denote invalidation too. In an address designed to sell his court-packing scheme to Congress, Roosevelt lamented that "[s]tatutes which the Congress enacts are set aside or suspended for long periods of time" by federal courts. Roosevelt was upset that courts were preventing whole pieces of New Deal legislation from taking effect, not merely exempting individual plaintiffs from compliance. To him, and to the public he addressed, "set aside" meant to invalidate entirely.

B. The APA's Text Undergirds the Judicial Consensus Favoring Vacatur

That background informs the meaning of APA Section 706, which directs that "the reviewing court shall . . . hold unlawful and set aside agency action" that is "found to be" unlawful. The APA's definitions

section states that "'agency action' includes the whole or a part of an agency rule." As Mila Sohoni explained, "the statute makes agency action the *object* of the court's review." This posture replicates the "appellate review model" in which an appellate court takes an inferior court's judgment as the object of its review and sets it aside—that is, invalidates it—if the appellate court finds the judgment is unlawful.

Another way to understand this review structure is by analogy to bankruptcy law. When a federal court reviews agency action under the APA, the relationship between the court and agency is like that between an Article III federal district court and the Article I bankruptcy court under its supervision. The inferior actor, be it an agency or bankruptcy court, takes the first shot at determining legal duties and obligations, but that determination has no force if the reviewing court finds it inconsistent with law. Both scenarios ensure that the final arbiter of legal rights and obligations is an actor that the Constitution itself creates and entrusts with Article III judicial power.

Jonathan Mitchell agrees that "[u]nlike judicial review of statutes, in which courts enter judgments and decrees only against litigants, the APA . . . [goes] further by empowering the judiciary to act directly against the challenged agency action." This statutory design "enables the judiciary to formally revoke an agency's rules . . . in the same way that an appellate court formally revokes an erroneous trial-court judgment."

In fact, the majority of the APA's drafters assumed that most administrative agencies would regulate through quasi-judicial adjudication, not rulemaking. As Professor Reuel Schiller observed, "[b]efore the 1960s agencies acted mainly through case-by-case adjudications," and "[m]ost traditional administrative actions—ratemaking, for example—were based on judicial models."[2] The New Deal expansion of administrative agencies may be understood as a proliferation of what looked to Congress like a cornucopia of Article I courts. Given that "[a]dministrative proceedings looked like mini-trials, where the rights of individual actors were adjudicated," it is not surprising that "critics of the Roosevelt administration, who aggressively pushed for the passage of the APA, focused their energies on making agency adjudications more like common law trials."[3] It is also clear that the judicial review provisions of the APA re-constitutionalized agencies by placing them in an appellate-review chain of command under Article III courts. When an Article III court sets aside an unlawful

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[2] Reuel E. Schiller, *Rulemaking's Promise: Administrative Law and Legal Culture in the 1960s and 1970s*, 53 ADMIN. L. REV. 1139, 1145 (2001).

[3] *Id.* at 1145–46.

agency action, be it a narrow adjudicatory order or a nationwide rule, that action ceases to have any force.

Contrary readings of Section 706's "set aside" language are implausible. Best read, it cannot mean, as Professor John Harrison argued, that a court should only decline to apply a rule to the parties who challenged it. The statutory text instructs courts to "set aside" an unlawful "rule," not enjoin agency personnel from enforcing the rule against parties. In defining "agency action," the APA equates an agency "rule" with an "order" produced through trial-like agency adjudication. It then instructs courts to "set aside" agency actions that are unlawful. Congress thus drew the easy analogy between judicial review of lower court orders and court-like agency adjudication orders and prescribed the same remedy for both. It then extended this appellate review analogy to review of agency rules as well.

The fact that everyone in 1946 expected agencies to do most of their regulating through court-like adjudication orders rather than quasi-legislative rulemaking does not mean that agency rulemaking stands outside the appellate-review model.[4] For one thing, agencies cannot skirt judicial review by regulating more people with less process than Congress expected in the 1940s. Moreover, by the time of the APA, agencies had long been promulgating regulations with nationwide scope through individual actions. They simply called these regulations "orders" instead of "rules," and courts had granted universal set-aside relief against them in at least three pre-APA cases. In the illustrative example of *United States v. Baltimore & Ohio Railroad Co.*, the Supreme Court affirmed a three-judge district court's ruling that an Interstate Commerce Commission "order" requiring railroads to install a power reverse gear on their locomotives be "vacated, set aside, and annulled," and that its enforcement be "perpetually enjoined." The Congress that passed the APA understood that courts would review and vacate agency action that sought to regulate nationally. Indeed, the APA commands courts to do so.

Another flawed textual argument against universal APA remedies is that the APA sets forth remedies in Section 703, not Section 706, and so Section 706's "set aside" language does not address remedies at all. Solicitor General Elizabeth Prelogar advanced this argument at oral argument in *United States v. Texas*, echoing Professor Harrison. Section 706, however, authorizes courts, in appropriate circumstances, to "compel agency action," which is most definitely a remedy. And the APA's structure leads one to expect to find final remedies in Section 706,

[4] *See* Samuel L. Bray, *Multiple Chancellors: Reforming the National Injunction*, 131 HARV. L. REV. 417, 425–45, 438 n.121 (2017).

right after Section 705 introduces (some universal) interim remedies. Section 703, on the other hand, is labeled "[f]orm and venue of proceeding," and makes no reference to remedies besides once using the word "injunction" to specify that the permissible "form[s] of legal action[ ] includ[e] actions for . . . writs of prohibitory or mandatory injunction or habeas corpus." Section 703's authorization of a specialized form of proceeding that happens to have the word "injunction" in its name does not make Section 703 a remedies provision, let alone an exclusive one. The APA's text and structure suggest that courts have been right all along—they should ordinarily vacate unlawful administrative rules and remand them to the agency for reconsideration.

II. The APA Authorizes Universal Interim Relief

Less has been written on the interim remedies available under the APA, although the importance of those remedies has only increased. Indeed, a growing number of high-profile challenges to agency action have reached the Supreme Court not through petitions for certiorari, but in an emergency posture.[5] As Justice Neil Gorsuch has observed, in this setting, interim remedies control the challenged action's fate for months or years during litigation, and often practically become final remedies when litigation outlives the challenged action. This Part shows that the APA grants courts authority to stay agency rules from taking effect pending appeal to the Supreme Court or denial of certiorari, even if

[5] *See, e.g.*, Ohio v. EPA, 144 S. Ct. 2040, 2058 (2024) (granting stay application for stay of ozone transport regulations); Garland v. Blackhawk Mfg. Grp., 144 S. Ct. 338 (2023) (challenging the regulation of gun parts as "firearms"); Biden v. Nebraska, 143 S. Ct. 2355 (2023) (rejecting student loan nullification); United States v. Texas, 143 S. Ct. 1964, 1980–86 (2023) (Gorsuch, J., concurring in judgment) (criticizing universal remedies in a challenge to immigration guidelines); Nat'l Fed'n of Indep. Bus. v. Dep't of Lab, 142 S. Ct. 661 (2022) (addressing the COVID-19 vaccine mandate). Still more high-profile litigation reaches the lower courts in an emergency posture. *See, e.g.*, The Enhancement and Standardization of Climate-Related Disclosures for Investors; Delay of Effective Date, 89 Fed. Reg. 25,804 (April 12, 2024) [hereinafter Climate-Related Disclosures; Delay of Effective Date] (staying rule requiring registrants to provide certain climate-related information in registration statements and annual reports in response to Eighth Circuit litigation seeking stay); Texas v. EPA, 2024 WL 3384818, at *1 (D.C. Cir. July 9, 2024); *see also* W.V. by & through Morrisey v. U.S. Dep't of Treasury, 59 F.4th 1124 (11th Cir. 2023) (granting a permanent injunction against a Treasury rule); Texas v. EPA, 662 F. Supp. 3d 739 (S.D. Tex. 2023), *appeal dismissed*, 2023 WL 8295928 (5th Cir. Oct. 6, 2023); Kentucky v. Fed. Highway Admin., 2024 WL 1402443, at *1 (W.D. Ky. Apr. 1, 2024).

courts lack authority to universally enjoin statutes and direct presidential action.

The textual argument for universal interim remedies under the APA is perhaps even stronger than that for universal final remedies. The APA's interim remedies provision, Section 705, grants that "the reviewing court . . . may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." This grant of judicial discretion to "postpone the effective date of an agency action" combines with the APA's definition of "agency action," which includes a "rule" or "order," to make a challenged agency action itself an object of interim remedies, just as agency action is the object of final remedies.

The operative language makes sense only in terms of a universal interim pause. "[P]ostpone the effective date of an agency action" is most naturally read to mean that the agency action—a rule or order—takes no effect as to anyone anywhere, not that it takes effect as to everyone but the parties to a legal challenge. And reason accords with text: only universal interim remedies match the scope of final relief available, as is necessary to protect parties adequately. Moreover, these universal remedies avoid the practical difficulties of carving individual parties or jurisdictions out of a rule or order applicable elsewhere. Put plainly, since Section 706 creates the universal final remedy of vacatur, it only makes sense that Section 705 would create a universal interim remedy capable of preserving the possibility of a universal final remedy. One would expect this congruence between interim and final remedies.

Moreover, when a court determines that tailored relief is practicable and otherwise appropriate, Section 705 authorizes the court to issue a preliminary injunction tailored as "necessary and appropriate . . . to preserve the status quo or rights pending conclusion of the review proceedings." The APA presents courts with injunctive relief as an *alternative option* to postponing a rule's effective date, which strongly suggests that a judicially postponed agency action is postponed universally, not only so far as necessary to preserve the status quo (whatever that might mean) or the rights of parties.

A final textual hint lies in Section 705's parallel grant of authority to an agency to "postpone the effective date of action taken by it, pending judicial review." The SEC recently exercised this power in response to legal challenges to its rule requiring companies to provide climate-related information in their registration statements and annual reports.[6] The agency decided to stay the rule on its own initiative

[6] Climate-Related Disclosures; Delay of Effective Date, 89 Fed. Reg. at 25,804.

pending final judicial review. Just as an agency may postpone its rule or order wholesale, so may a reviewing court. That is the only sensible reading of the APA's deployment of the same phrase in the same section to describe the interim relief available from agencies and courts.

Again, judicial precedent shows practice agrees with the text. The Supreme Court itself has universally stayed two agency actions pending final merits review in recent years, showing that it understands the APA to authorize interim relief that runs against a rule itself. In 2016, it stayed the EPA's "Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units." And in 2022, the Court stayed OSHA's vaccine mandate. In the latter case, the Court remarked without criticism that the Fifth Circuit had stayed the agency action universally in earlier proceedings. Justice Kavanaugh, joined by Justice Amy Coney Barrett, addressed this practice directly in his concurrence in the Court's narrowing of a district court's stay against an Idaho statute. He distinguished universal stays of statutes from stays against "new federal regulations, given the text of the APA."

The APA's text and the behavior of courts and agencies confirm that courts may issue universal interim remedies against unlawful agency action.

III. The Separation of Powers Requires the Availability of Universal Judicial Remedies for Unlawful Agency Action

Applying the plain meaning of the APA's text and history makes sense in the broader separation of powers scheme of the Constitution. The Constitution establishes the federal judiciary as a branch of government coequal with the legislative and executive. Thus, it is unsurprising that no provision of the Constitution authorizes the court to "set aside" the work of Congress when it reviews a statute for conflict with the Constitution. Instead, recall that constitutional review involves what are essentially choice-of-law principles. That is because both the Constitution and any duly enacted statute have the status of "law," but, as Justice Clarence Thomas has observed, one has a principled and textual right-of-way in any possible collision.

Administrative agencies, by contrast, are not creatures of constitutional creation, but statutory hybrids within the executive branch, exercising delegated powers that are considered mixed quasi-executive, quasi-judicial, and quasi-legislative in nature. And while an "agency action" might look like law because it has legal consequences for regulated parties, it is not "law" in the same sense that the Constitution and federal or state statutes are law. Rather, an agency action is the executive branch's enforcement of the laws enacted by Congress reduced

to a rule or an order. As the Supreme Court has noted, "an agency literally has no power to act . . . unless and until Congress confers power upon it." Thus no agency's regulation can "'operate independently of' the statute that authorized it."

Nevertheless, agency rulemaking binds parties with the force of legal consequences without undergoing the compromise-inducing ordeal of passage through both houses of Congress and presentment to the President. This constitutional process restrains exercises of pure legislative power and commands greater judicial respect for legislative commands that survive the process. Maintaining the Constitution's allocation of powers requires courts to counterbalance this relative lack of front-end checks on agency action with relatively greater judicial review on the back end.

To see why that is so, consider the alternative. If courts could not universally vacate agency action that unlawfully regulates with universal effect, then the Constitution's allocation of powers would be distorted by executive branch "lawmakers" insufficiently accountable to either congressional or judicial review. And indeed, there is much to be said for the argument that Congress has legislated relatively less as executive agencies have issued more rules.

It is, therefore, logically symmetrical that the APA authorizes courts to issue remedies running against an agency rule itself, even when courts may not issue universal remedies against statutes that are subject to greater front-end checks. Congress simultaneously gave agencies authority to make rules with universal effect and courts commensurate power to prevent the universal injustice of an unlawful rule by issuing universal relief. If the Constitution permits the first move, separation of powers requires, or at least permits, as Justice Byron White suggested, the second move as well. Otherwise, agency action would evade judicial review as to all regulated persons who do not join a successful lawsuit. Such a system would deny full protection of law to those without the resources and wherewithal to challenge unlawful regulation. It would also create a legal patchwork that would undermine the effectiveness of many rules and greatly complicate compliance and enforcement efforts.

Nevertheless, some, including Professor Samuel Bray and Chief Judge Jeffrey Sutton of the Sixth Circuit, have suggested that universal APA remedies exceed the limits of the judicial power that Article III vests in the federal judiciary.[7] These critics have argued that federal courts may not hand out remedies "in the abstract" because Article III empowers them only to resolve concrete "Cases" or "Controversies." A

[7] *See* Bray, *supra* note 4, at 433, 471–72.

universal remedy might exceed that limit to the extent it goes beyond redressing the injury in the case or controversy presented. Samuel Bray's work provides historical grounding for this critique by showing that principles of traditional equity did not permit universal injunctions.

Universal remedies under the APA, however, remain within Article III limits because they are legal, not equitable, remedies created by Congress and available only to resolve true cases or controversies. Critics of universal remedies are correct that the separation of powers generally prohibits remedies that reach beyond parties except where equity would have permitted at the Founding. Courts may not invent new equitable remedies that were unknown in England and America before the Founding because that would allow federal judges to unilaterally expand their own power into the legislative realm of general policymaking. Since only the legislature has the power to bind the sovereign people at large, Congress is the proper institutional actor to decide how far judicial remedies can reach before becoming quasi-legislative. These principles make remedies created by Congress (like stay and vacatur of agency action) presumptively constitutional and remedies invented by courts (like universal injunctions) constitutionally suspect.

History explains why remedies created by statute are presumptively lawful "legal" remedies in the fullest sense, whereas court-created remedies are best understood as remedies in "equity" and strictly conscribed. In medieval England, Parliament possessed absolute power to create new causes of action by statute.[8] No separation of powers concerns were conceivable because Parliament was both the legislature and the high court. Any expansion of judicial remedies approved by statute was, by definition, lawful. Equity, by contrast, was an extra-legal device by which the King's appointed Chancellor could, within broad limits, supersede the requirements of law that bound courts when he believed that justice so required. In this sense, the Chancellor could "make law" independent of the courts and Parliament.

When the U.S. Constitution created a separate legislature and judiciary, it also created a potential separation of powers problem by placing the powers of equity in the hands of federal judges. If courts expanded equity to include remedies unknown at the Founding, the federal judiciary would gain a share of legislative power. To avoid potential separation of powers problems, federal courts must respect the traditional limits on equitable remedies that Samuel Bray identified, which did not permit courts to issue sweeping injunctions impacting the

[8] See JOHN BAKER, AN INTRODUCTION TO ENGLISH LEGAL HISTORY 221, 354 (2019).

ability of a separate branch of government to enforce a statute.[9] Statutory remedies, by comparison, present fewer separation of powers concerns because they represent the legislature's judgment that those remedies do not encroach on legislative power. Thus, broad statutory remedies like those in the APA and Federal Rule of Civil Procedure 23, are not subject to the traditional limits of equity. They simply are not equitable remedies.

Some might argue that universal remedies might nonetheless exceed the judicial power of Article III. If so, even a statute could not authorize universal remedies because Congress may not expand the Constitution's limits on judicial power. And indeed, according to Supreme Court doctrine, Article III contains some limits on how far Congress can expand judicial remedies. Congress could not, for example, delegate to courts authority to write statutes in the form of judicial opinions addressed to the public at large, or to give government officials legal advice. But judicial review of agency action does not depend on Congress expanding Article III. It comports with Article III's case or controversy requirement, avoids advisory opinions, and gives courts no quasi-legislative power to create new, generally applicable legal obligations.

The Constitution bars Congress from authorizing courts to declare law independent of a concrete case or controversy because that would commingle legislative and judicial power by allowing courts to "prescribe[ ] the rules by which the duties and rights of every citizen are to be regulated" or to issue advisory opinions. But judicial vacatur of an unlawful agency rule never approaches these boundaries. It is available only if a party "aggrieved by [the] agency action" brings a concrete case, and it never declares new policies, just prevents new policies from taking effect. Nor does it purport to undo any act of Congress. It is inherently judicial power in the sense that it is a strictly negative power, activated only by a concrete dispute, to prevent subordinate actors from transgressing the boundaries of law. In this sense, the judiciary acts as a faithful agent of Congress in reviewing executive branch agencies' actions. And an opinion vacating a rule is not advisory. The very reason for recent objections to judicial vacatur is that it has too significant an effect. These essential characteristics of stay and vacatur of agency action show that it is precisely the type of power that Article III contemplates.

Some of the anxiety about the universal scope of APA remedies, which gets inaptly expressed as an Article III concern, may be resurfacing doubt about the constitutionality of agency rulemaking.

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[9] *See* Bray, *supra* note 4, at 420–21, 425–28.

Analyzing APA review through the appellate review model illustrates this point. In that model, a trial court judgment ordinarily affects only parties to the underlying suit. Thus, only those parties are affected when an appellate court invalidates that judgment. There is a correct intuition that the appellate court in this scenario could not act with nationwide effect without exceeding its authority. To reach nationwide results, the appellate court would need to reach beyond the trial-court judgment before it, by purporting to invalidate other similar trial-court judgments or decree binding rules of primary conduct in the abstract.

But the intuition that nationwide effect must exceed rightful judicial authority leads critics astray when a federal court sits in appellate-style review of agency action. Here, the judgment below—the agency rule under review—had a nationwide effect, unlike the party-bound effects of true court judgments. Thus, when a court invalidates an agency rule, that invalidation has a nationwide effect too. That may seem strange, but the strangeness lies in the scope of regulatory authority the "lower court" (the agency) exercised, not in the reviewing court's routine exercise of judging only the object placed before it. What really triggered the intuition that something illegal is ongoing was the agency action.

This again stands in contrast to statutes that have nationwide effect but came into being through procedures designed to ensure something like national consensus: bicameralism and presentment. Such federal law passes a gauntlet far more daunting than informal (notice-and-comment) rulemaking. So again, to reconstitutionalize Congress's choice to give an agency subordinate to a unitary executive (the President) the power to make nationwide pronouncements, Congress placed those agencies under the direct appellate-style review of the federal judiciary. If Congress has the power to adopt statutes that create agencies with nationwide quasi-legislative power, it surely has the power to adopt a statute that cabins such nationwide quasi-legislative power.

Also worth noting is that the injunctive class action mechanism from Federal Rule of Civil Procedure 23—a dramatic expansion of equitable remedies—is likely unconstitutional if Congress may not expand remedies beyond traditional limits. And there is no principled line to be drawn between Rule 23's expansion of injunctive relief to third parties only before the court in a representative capacity and the APA's choice to broaden relief by directing remedies at agency action itself, rather than expand the equitable tradition of enjoining the officers charged with carrying out agency action. If anything, Rule 23 is more suspect because it expands courts' power to bind private actors by

injunction, whereas the APA's universal remedies only create a power to negate agency action that was authorized by statute in the first place.

The APA's text, historical background, and constitutional principles all demonstrate that courts have correctly concluded that the "ordinary result" for unlawful rules is "that the rules are vacated—not that their application to the individual petitioners is proscribed."[10]

IV. Consequences Stemming from the Distinction Between Equitable Remedies and the APA Remedies of Stay and Vacatur

Contemporary debates surrounding universal injunctions and stays of new laws do not apply to APA remedies. It is easy to conflate the APA remedies of stay and vacatur of agency action with the equitable remedies of stay and injunction (preliminary and permanent) against statutes and presidential action. But, the APA's judicial review provisions create a unique remedies paradigm that is independent of courts' inherent equitable powers and general grants of statutory authority. This Part differentiates the universal remedies available under the APA from universal injunctions and from stays against state and federal statutes. It shows that concerns about the latter judicial inventions say nothing about the legality or propriety of the APA's universal remedies.

A. The APA Offers the Universal Remedies of Stay and Vacatur, Which Are Distinct from Preliminary and Permanent Injunctions

The universal remedies that the APA makes available are different in kind from universal injunctions. Courts and litigants have sometimes confused this distinction, especially in the context of interim remedies, by using the terms "preliminary injunction" or "temporary restraining order" interchangeably with "stay." For example, the Supreme Court recently decided an application for a partial stay of a rule implementing Title IX as though it were a request for a preliminary injunction. And the Eleventh Circuit has generated still more confusion by purporting to apply the traditional stay factors to applications for injunctions pending appeal, while also heightening the likelihood-of-

[10] *See also* Data Mktg. P'ship, LP v. Dep't of Lab., 45 F.4th 846, 859–60 (5th Cir. 2022); Regents of the Univ. of Cal. v. U.S. Dep't of Homeland Sec., 908 F.3d 476, 511 (9th Cir. 2018), *rev'd on other grounds, vacated in part sub nom.* Dep't of Homeland Sec. v. Regents of the Univ. of Cal., 140 S. Ct. 1891 (2020); Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Eng'rs, 781 F.3d 1271, 1290 (11th Cir. 2015).

success prong in apparent recognition of the extraordinary nature of preliminary injunctive relief. The Supreme Court's jurisprudence helps elucidate the difference between these remedies.

The Supreme Court's comparison of stays and preliminary injunctions in *Nken v. Holder* most visibly illustrates the important difference between stays and preliminary injunctions. To receive a stay, the Court explained, a party must show a likelihood of success on the merits, irreparable injury absent a stay, and that the private and public interests favor a stay (though it remains an open question whether the likelihood-of-success prong requires a showing of "certworthiness" for "emergency" stay applications in the Supreme Court). The Court has acknowledged that "[t]here is substantial overlap between these and the factors governing preliminary injunctions," but has maintained that stays are distinct from preliminary injunctions. "[A] stay operates upon" a "proceeding itself," the *Nken* Court noted, "either by halting or postponing some portion of the proceeding, or by temporarily divesting an order of enforceability." It does not directly bind any person to act or refrain from acting.

The *Nken* Court wrote in the context of a stay of a judicial proceeding, but the Court confirmed that the *Nken* standard applies to a request to stay administrative action this term in *Ohio v. EPA*, as other courts have done in the past. Section 705's grant of authority for courts to "postpone the effective date of an agency action" makes agency action the "proceeding" against which a stay operates. So, it is no surprise that the Supreme Court has recognized universal stays of agency action as an appropriate interim remedy. By contrast, an injunction, whether preliminary or permanent, "is a judicial process or mandate operating *in personam*." It "is directed at someone, [not something,] and governs that party's conduct." And because an injunction infringes the enjoined person's liberty, it must be as narrow as justly possible. As Samuel Bray has observed, historically, injunctions did "not control the defendant's behavior against nonparties."[11] Thus, a stay must be as broad as the action or proceeding it operates against, whereas the proper scope of an injunction is to prohibit the enjoined party (whether private actor or government official) from taking the unlawful action plaintiffs complained of.

Importantly, that distinction holds as to final APA remedies because vacatur, just like a stay, acts against agency action itself.

[11] Bray, *supra* note 4, at 421.

B. The APA's Universal Remedies Do Not Raise Significant Separation of Powers and Federalism Issues

The nature of the action that APA remedies run against is as significant as the nature of the remedies themselves when it comes to understanding why the APA's universal remedies are lawful. APA remedies run against agency action. And agency action is, at best, a quasi-constitutional chimera of quasi-legislative, quasi-executive, and quasi-judicial power, as the Court recognized in *Humphrey's Executor v. United States*, and as Justices Robert Jackson and White have suggested. This hybrid nature carries two important implications for the legality of universal APA remedies.

First, it means that judicial invalidation of agency action does not unbalance the tripartite separation of powers the Constitution establishes. Judicial suspension of or refusal to apply federal legislation always results in a clash of the coordinate departments of government since a statute (unlike an agency action) is the purely legislative act of a coequal branch of government. Universal remedies against enforcement of federal statutes interfere with what could reasonably be viewed as the Constitution's main focus—Congressional action. They tend toward power imbalance by shifting power from Congress to the courts. On the other hand, the APA's universal remedies reduce the power of governmental actors that are unknown to the Constitution. They serve to return the allocation of federal power closer to the Constitution's equilibrium point. They do this by using an enactment of Congress (the APA) to review and sometimes negative the actions of creatures of Congress (executive branch agencies). Universal APA remedies thus benefit separation of powers principles. In contrast, separation of power principles suffer when these universal remedies touch on federal statutes.

Second, the federal origin of agency action meaningfully distinguishes it from state laws that parties challenge in federal court. The APA directs review only of federal government action, so remedies that wholly incapacitate that action do no violence to federalism. When federal courts issue stays against enforcement of state laws, however, they irreparably infringe the States' retained lawmaking power, harming the Constitution's vertical balance. So, the federalism reasons to avoid federal court-issued remedies against state laws have no purchase when it comes to the APA's universal remedies.

C. The APA Does Not Authorize Courts to Enjoin Presidential Action

Equally important is that APA universal remedies face none of the problems unique to universal injunctions directed against presidential action. The APA authorizes universal remedies only against "agency action," which does not include presidential action. In fact, the APA does not authorize judicial review of presidential action at all. A different framework of constitutional review applies instead. So, the legal arguments against universal injunctions of presidential action do no harm to universal remedies against agency action under the APA.

The primary argument against universal injunctions of presidential action is that no source of law authorizes them. No statute grants district courts general power to issue universal injunctions, nor does the courts' inherent constitutional authority include any such power. Thus, courts lack general power to enjoin executive action. But courts do enjoy express statutory authorization to issue stays and vacatur of *agency* action under the APA. And this Article has already explained that these remedies are consistent with the separation of powers and Article III limits that might prevent Congress from authorizing universal injunctions against presidential action by statute. As elsewhere in the universal remedies debate, APA remedies stand above the fray. It should be little wonder, then, that courts have universally accepted without question that the APA provides universal remedies against agency action.

Conclusion

The APA is best understood as making universal remedies the default relief for unlawful agency action. The legal profession should not allow separate questions about universal injunctions to unsettle this consensus. APA remedies do not face the most serious legal problems that federal courts create when they enjoin enforcement of statutes beyond their jurisdiction (or, in the case of state laws, created by a separate system of government). If courts, lawyers, and scholars want to debate the legality of both universal remedies against agency action and universal injunctions, they must have two separate debates. This Article has focused on the APA debate to emphasize that that debate is largely settled, and rightly settled too.

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T. Elliot Gaiser is the Solicitor General of Ohio.

Mathura J. Sridharan is the Director of Ohio's Tenth Amendment Center and serves as a Deputy Solicitor General in the Ohio Attorney General's Office.

Nicholas A. Cordova is an associate at Boyden Gray PLLC and former Simon Karas Fellow to the Ohio Solicitor General.

EXHIBIT 12

Letter from Elizabeth Warren et al. to FDA
(Nov. 18, 2022)

United States Senate
WASHINGTON, DC 20510

November 18, 2022

Dr. Robert M Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Califf:

In the wake of the Supreme Court's devastating decision in *Dobbs v. Jackson Women's Health Organization* to eliminate the right to an abortion,[1] we urge you to immediately act to defend Americans' fundamental reproductive rights. We respectfully request that you consider the following three actions to protect and expand access to medication abortion: (1) finalize the updated Risk Evaluation and Mitigation Strategy (REMS) for Mifepristone, (2) lift remaining medically unnecessary REMS restrictions, and (3) work with drug sponsors to add a miscarriage management indication for Mifepristone taken with misoprostol.

For over two decades, women have been safely and effectively using medication abortion – Mifepristone and misoprostol – to terminate a pregnancy.[2] But the Supreme Court's reckless decision to overturn *Roe v. Wade* now endangers millions of women in this country who are facing restrictions to lifesaving care and rights.[3]

Soon after the Supreme Court's *Dobbs* decision, in July 2022, President Biden released an Executive Order to protect access to reproductive health care services.[4] In August 2022, the Department of Health and Human Services (HHS) responded by publishing a report that provided an "action plan to protect and strengthen reproductive care."[5] The HHS report included a recommendation to expand access to medication abortion through FDA finalization of updated REMS for Mifepristone "that have been found to be safe and effective."[6] We are writing to ask you to consider the following recommendations, specifically, that you:

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[1] Dobbs v. Jackson Women's Health Organization, 597 U.S. _ (2022).
[2] Guttmacher Institute, "Medication Abortion," February 2021, https://www.guttmacher.org/evidence-you-can-use/medication-abortion.
[3] New York Times, "Medical Impact of Roe Reversal Goes Well Beyond Abortion Clinics, Doctors Say," Kate Zernike, September 10, 2022, https://www.nytimes.com/2022/09/10/us/abortion-bans-medical-care-women.html.
[4] White House, "FACT SHEET: President Biden to Sign Executive Order Protecting Access to Reproductive Health Care Services," press release, July 8, 2022, https://www.whitehouse.gov/briefing-room/statements-releases/2022/07/08/fact-sheet-president-biden-to-sign-executive-order-protecting-access-to-reproductive-health-care-services/.
[5] Department of Health and Human Services, "Health Care Under Attack: An Action Plan to Protect and Strengthen Reproductive Care," August 2022, p. 1, https://www.hhs.gov/sites/default/files/hhs-report-reproductive-health.pdf.
[6] Department of Health and Human Services, "Health Care Under Attack: An Action Plan to Protect and Strengthen Reproductive Care," August 2022, p. 6, https://www.hhs.gov/sites/default/files/hhs-report-reproductive-health.pdf.

1. **Finalize the Updated Risk Evaluation and Mitigation Strategy (REMS) for Mifepristone.** In December 2021, FDA conducted a scientific and evidence-based review of the Mifepristone REMS program and announced it would modify the existing REMS for Mifepristone, including eliminating the medically unnecessary in-person dispensing requirement.[7] This modification would expand access to medication abortion by allowing clinicians to dispense Mifepristone by mail order and/or for patients to obtain access to Mifepristone at retail pharmacies.[8] However, FDA is still processing the changes to the REMS and has not finalized them yet, despite the fact that manufacturers have already made their required submissions to FDA for approval.[9] We encourage you to finalize your review of manufacturers' plans to certify pharmacies and the updated REMS, especially as we advance closer to the 180-day deadline that FDA has to review or modify submissions.[10] It is crucial that you act as soon as possible to allow patients to access Mifepristone via certified mail delivery and at retail pharmacies. Until you finalize the updated REMS, we ask FDA to continue its policy of exercising enforcement discretion (put in place at the beginning of the COVID-19 pandemic) to protect access to medication abortion, regardless of when the COVID-19 public health emergency ends.[11]

2. **Consider Lifting Remaining Medically Unnecessary REMS Restrictions.** Distributing Mifepristone as a normal prescription, without REMS, is safe and effective.[12] As you prepare to finalize the updated REMS for Mifepristone that you announced almost a year ago, we ask that you continue to follow the science and reconsider the remaining REMS, lifting any remaining medically unnecessary restrictions.[13] FDA frequently reviews REMS "at periodic intervals following REMS approval."[14] You acknowledged in December 2021 that FDA modified the REMS for Mifepristone "after reviewing the data and information submitted by the applicant … and after taking into consideration the

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[7] Food and Drug Administration, "Mifeprex (mifepristone) Information," https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information.

[8] The American College of Obstetricians and Gynecologists, "Understanding the Practical Implications of the FDA's December 2021 Mifepristone REMS Decision," news release, March 28, 2022, https://www.acog.org/news/news-articles/2022/03/understanding-the-practical-implications-of-the-fdas-december-2021-mifepristone-rems-decision; Congressional Research Service, "Medication Abortion: A Changing Legal Landscape," Jennifer A. Staman and John O. Shimabukuro, October 5, 2022, https://crsreports.congress.gov/product/pdf/LSB/LSB10706.

[9] Inside Health Policy, "Abortion Pill Makers Send FDA Detailed Proposal To Expand Access," Beth Wang, July 12, 2022, https://insidehealthpolicy.com/inside-telehealth-daily-news/abortion-pill-makers-send-fda-detailed-proposal-expand-access.

[10] New England Journal of Medicine, "Sixteen Years of Overregulation: Time to Unburden Mifeprex," Mifeprex REMS Study Group, February 23, 2017, https://www.nejm.org/doi/10.1056/NEJMsb1612526.

[11] Letter from Food and Drug Administration to American College of Obstetricians and Gynecologists, April 12, 2021, https://www.aclu.org/letter/fda-response-acog-april-2021; Washington Post, "Abortion Pills by mail are safe. The FDA finally acknowledged it," Daniel Grossman, December 20, 2021, https://www.washingtonpost.com/outlook/2021/12/20/telemedicine-abortion-fda-safe/.

[12] New England Journal of Medicine, "Abortion Safety and Use with Normally Prescribed Mifepristone in Canada," Laura Schummers, Elizabeth K. Darling, Sheila Dunn, Kimberlyn McGrail, Anastasia Gayowsky, Michael R. Law, Tracey-Lea Laba, Janusz Kaczorowski, and Wendy V. Norman, January 6, 2022, https://www.nejm.org/doi/full/10.1056/NEJMsa2109779.

[13] *Id.*

[14] Food and Drug Administration, "Frequently Asked Questions," https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems.

safety data that had become available since the initial approval of Mifeprex in 2000."[15] Given this example, we urge you to proactively review the remaining REMS to determine if any restrictions placed on the prescription and distribution of Mifepristone, including patient consent forms, are also medically unnecessary.[16]

3. **Work with Drug Sponsors to Add a Miscarriage Indication for Mifepristone with Misoprostol.** To further protect reproductive health and rights, we urge you to work with drug sponsors to add an additional indication to the Mifepristone with misoprostol label: use for miscarriage management.[17] As many as 26 percent of all pregnancies end in miscarriage,[18] and Mifepristone, when taken with misoprostol, significantly improves the management of early pregnancy loss and results in fewer complications.[19] Yet, many patients in states that have restricted access to medication abortion have reported being denied these medications to treat their miscarriages – to devastating effect.[20] Coordinating with drug sponsors to update the Mifepristone with misoprostol label will help ensure that patients experiencing miscarriages are not denied access to this medication.[21] Until you update the label, we ask FDA to exercise enforcement discretion regarding the use and distribution of Mifepristone under its current REMS and indication.

Since the Supreme Court overturned *Roe v. Wade,* states have continued to place radical bans and restrictions on abortion.[22] As states implement new restrictions, it is more important than ever that you take immediate steps to expand access to medication abortion. We encourage and support your efforts to protect access to abortion and reproductive rights across the nation. To continue coordinating our efforts, we request a staff-level briefing or written response by December 1, 2022 that provides a detailed update on FDA's actions regarding the REMS for Mifepristone and the Mifepristone with misoprostol label.

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[15] Letter Food and Drug Administration Center for Drug Evaluation and Research to American Association of Pro-Life Obstetricians and Gynecologists and American College of Pediatricians, December 16, 2021, https://www.regulations.gov/document/FDA-2019-P-1534-0016.

[16] New England Journal of Medicine, "Sixteen Years of Overregulation: Time to Unburden Mifeprex," Mifeprex REMS Study Group, February 23, 2017, p. 793, https://www.nejm.org/doi/10.1056/NEJMsb1612526.

[17] Citizen Petition from American College of Obstetrician and Gynecologists to Food and Drug Administration, October 4, 2022, https://emaaproject.org/wp-content/uploads/2022/10/Citizen-Petition-from-the-American-College-of-Obstetrician-and-Gynecologists-et-al-10.3.22-EMAA-website.pdf.

[18] National Library of Medicine, "Miscarriage," Carla Dugas and Valori H. Slane, June 27, 2022, https://www.ncbi.nlm.nih.gov/books/NBK532992/.

[19] American College of Obstetricians and Gynecologists, "Early Pregnancy Loss," practice bulletin, November 2018, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss; New England Journal of Medicine, "Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss," Courtney A. Schreiber, Mitchell D. Creinin, Jessica Atrio, Sarita Sonalkar, Sarah J. Ratcliffe, and Kurt T. Barnhart, June 7, 2018, https://pubmed.ncbi.nlm.nih.gov/29874535/.

[20] Politico, "Patients face barriers to routine care as doctors warn of ripple effects from broad abortion bans," Alice Miranda Ollstein and Daniel Payne, September 28, 2022, https://www.politico.com/news/2022/09/28/abortion-bans-medication-pharmacy-prescriptions-00059228.

[21] The 19th, "Label change for mifepristone could reduce barriers to care for miscarriages, advocates say in petition to FDA," Jennifer Gerson, October 4, 2022, https://19thnews.org/2022/10/mifepristone-miscarriage-label-change-fda-petition/.

[22] Axios, "Where abortion has been banned now that Roe v. Wade is overturned," Oriana Gonzalez and Jacob Knutson, October 11, 2022, https://www.axios.com/2022/06/25/abortion-illegal-7-states-more-bans-coming.

Thank you for your prompt attention to this urgent matter.

Sincerely,

Elizabeth Warren
United States Senator

Bernard Sanders
United States Senator

Mazie K. Hirono
United States Senator

Kirsten Gillibrand
United States Senator

Angus S. King, Jr.
United States Senator

Chris Van Hollen
United States Senator

Edward J. Markey
United States Senator

Ron Wyden
United States Senator

Brian Schatz
United States Senator

EXHIBIT 13

Aria Bendix, *Why Abortions Rose After* Roe *Was Overturned*, NBC News (Nov. 26, 2024, at 2:00 PT)

— Abortions rose in the U.S. last year – an unexpected trend. Xinyue Chen for NBC News

ABORTION RIGHTS

Why abortions rose after Roe was overturned

Contrary to many predictions, abortions did not decline nationally after the Supreme Court's Dobbs decision. Here's what's behind the trend.

Nov. 26, 2024, 2:00 AM PST

By Aria Bendix

It seemed only logical after the Supreme Court overturned Roe v. Wade that abortion rates would go down and births would go up.

Instead, the opposite happened: Abortions went up last year and the country's fertility rate hit a historic low.

More than 1 million abortions were recorded in the United States in 2023 – the highest in a decade, according to the Guttmacher Institute, a research group that supports abortion access. So far this year, abortion rates have remained about the same as in the last six months of 2023, preliminary data show.

"The post-Dobbs world wasn't as bad as we expected," said Diana Greene Foster, a reproductive health researcher at the University of California, San Francisco. "It happened that people were denied abortions before Dobbs. It's likely happening after Dobbs, but not to the extent that I, at least, was worried about."Foster predicted in 2022 that a quarter of women who wanted abortions in states with bans would give birth instead. Now, she thinks the share might be somewhere in the low single digits.

What happened to keep the abortion rates from falling?

To answer that question, NBC News sought out the people and systems behind the trend – spending a day at an Illinois Planned Parenthood clinic, meeting with the Dutch doctor whose work was crucial to preserving access to abortion pills in the U.S., and speaking with key players from all corners of the abortion rights landscape: providers, researchers, abortion fund directors, advocates, lawyers, policy experts and anti-abortion groups.

— An abortion rights advocate cries outside the Supreme Court after it overturned Roe v. Wade on June 24, 2022. Frank Thorp V / NBC News

Much of the story, it turns out, comes down to a small network of medical providers who found ways to prescribe and ship abortion pills around the country from places where they're still legal. That was only possible because of significant action taken by the Food and Drug Administration during the pandemic, which allowed the pills to be dispensed via telemedicine. Then, in the wake of the ruling in Dobbs v. Jackson Women's Health Organization, eight states passed laws that protected providers from being sued for prescribing abortion pills virtually to people from other states.

"The obstacles are actually lower than before Dobbs," said Dr. Rebecca Gomperts, the Dutch physician who founded Aid Access, an organization that mails abortion medications to individuals who request them. "For people that didn't have the financial resources or the infrastructure, the logistical structures in place to go to a clinic ... I think the landscape now is much better."

Recommended

HEALTH

At meeting on Florida's plan to end school vaccine mandates, skeptics and doctors stand off

HEALTH

Triple-negative breast cancer vaccine shows promise in early clinical trial

Outrage over the Dobbs decision also spurred a wave of donations and educational campaigns that helped expand access to in-person abortions at clinics. Funds that provide financial support to people seeking to end their pregnancies used that money to help discount or cover the cost of abortions, including travel and lodging for those who crossed state lines. Abortion providers, meanwhile, got an influx of funding that enabled them to set up new clinics and extend hours in states where abortion is still legal.

"It was kind of all hands on deck after Dobbs to get people the information and access to make sure that these abortion bans were not going to stop people from being able to access care," said Serra Sippel, executive director of The Brigid Alliance, a service that provides abortion seekers with support for travel, food, lodging and child care.

Abortions in the U.S.

In excess of a million abortions were estimated to be performed in 2023, more than the reported count in any of the years in the past decade where data is available.

Notes: Figures are rounded to the nearest 10.
Source: Guttmacher Institute
Graphic: Joe Murphy / NBC News

Donald Trump's election victory, however, could change that new status quo. Abortion pills are a target for anti-abortion activists, who hope the incoming administration might revoke provisions that allow the medications to be prescribed via telehealth and mailed nationwide. When asked about that possibility, Karoline Leavitt, a Trump-Vance transition spokeswoman, told NBC News that "President Trump has long been consistent in supporting the rights of states to make decisions on abortion."

Still, advocates on both sides of the issue said they are gearing up for a fight.

"We were under no illusions that Dobbs was going to solve the problem," said Randall O'Bannon, director of education and research for National Right to Life, an organization that opposes abortion. "The work is still very much going to need to be done, and we don't expect that the other side is going to give up or quit trying."

How pills preserved abortion access

Raised in a harbor town in the Netherlands, Gomperts has dedicated her life to preserving abortion access. Over coffee during a visit to New York City, she spoke about the subject with a clinical sensibility – perhaps because of her

background as a physician, perhaps because of how often she has to assert her viewpoint.

In 1999, Gomperts founded an organization that transported women from places with restrictions to a ship in international waters to obtain abortions. She launched a global telemedicine abortion service six years later, then in 2018 started Aid Access, which is headquartered in Austria.

“We know that people are scared,” Gomperts said. “Because of all the misinformation out there, they think that they’re breaking the law, which they’re not. It’s legal for women to do their own abortions.”

— Dr. Rebecca Gomperts in New York on Oct. 14. Elise Wrabetz / NBC News

To obtain pills via Aid Access, people fill out a questionnaire, sign a consent form, email an image of their ID and pay $150 – though the bill is adjusted on a sliding scale. The pills usually arrive within five days of being prescribed.Since the Dobbs decision, Gomperts said, Aid Access has seen a tenfold increase in demand.

The group's operating model relies on several FDA policies. In 2016, the agency enabled mifepristone – one of the two pills used in medication abortions – to be used up to 10 weeks' gestation instead of seven. Three years later, it approved a generic form, which increased supply.

Then came the biggest change: In 2021, the FDA eliminated the requirement to dispense mifepristone in person.

By last year, medication abortions accounted for 63% of abortions nationwide, up from 53% in 2020, according to the Guttmacher Institute. The institute does not disclose which providers are represented in its estimate, but some medication abortions are left out, including in states with bans, so the numbers are likely an undercount.

The pharmaceutical company that makes mifepristone, Danco Laboratories, said it does not publicly share its sales data. GenBioPro, the company that makes the generic version, also declined to provide such numbers. At the time of the Dobbs decision, 19 states banned or restricted telehealth prescriptions of abortion pills. Aid Access bypassed those laws because it was based overseas – physicians in Europe prescribed the pills to patients in the U.S. via a pharmacy in India.

Once post-Dobbs "shield" laws protected some providers who prescribe pills to patients in states where abortion is banned, Aid Access switched to partnering with a U.S. pharmacy and providers. Other telemedicine groups also began offering the pills nationwide, including A Safe Choice and the Massachusetts Medication Abortion Access Project, both of which said most of their patients are in states with abortion restrictions.

"Aid Access created and provided a model for other providers to replicate – not just replicate, but to expand upon," said Dr. Remy Coeytaux, a representative for A Safe Choice.

— Mifepristone and misoprostol pills.

Erin Hooley / Chicago Tribune via Getty Images file

“Had this small network of physicians not done this, there wouldn’t be access to telemedicine abortion” in states with bans, he added.It’s no surprise that anti-abortion groups are keen on stopping this work, and want to see the FDA changes rolled back.

“The ability of women to get these drugs online now, without an in-person visit, because of what the FDA did has essentially circumvented any law that a state might pass,” said Dr. Christina Francis, the CEO of American Association of Pro-Life OBGYNs, an anti-abortion group.

A surge in interstate travel for abortions

Although procedural abortions are harder to obtain post-Dobbs, out-of-state travel is another reason why abortions rose last year.

Nationally, more than 171,000 people crossed state lines to obtain an abortion in 2023 – roughly double the number in 2020, according to the Guttmacher Institute. Illinois has seen more out-of-state abortions than any other state, a 71% increase from 2020 to 2023.

Nekia, 25, traveled to Illinois from Whitestown, Indiana, to obtain an abortion last year; she asked that her last name not be published because of privacy concerns.

Nekia said she found out she was pregnant just after her state’s abortion ban took effect in August 2023. At the time, she added, she was pursuing a master’s degree and working full-time in marketing, and money was painfully tight.

“The last thing I could afford to do was to have a pregnancy,” she said. “That was a big motivating factor for me. I was like, ‘Regardless of how hard it is to figure this out, I’m going to get it figured out, and I’m going to make sure that I get to Illinois so I can get this done.’”

Not being able to afford a child is the most commonly cited reason for seeking an abortion, and the majority of women who do so are mothers already. About half are below the poverty line.

Nekia traveled to a Planned Parenthood clinic in Champaign, Illinois, about 2½ hours away, but said coming up with the money for gas and the procedure was a struggle.

“It was just stressful,” she said. “It was a lot of thinking, a lot of anxiety. ... Maybe I shouldn’t do this. Maybe I should just carry to term, because it just feels like there’s so many obstacles.”

To her relief, she said, Planned Parenthood gave her a prepaid gas card and discounted her procedure.

— Abortion rights demonstrator Amanda Herring and her 1-year-old son, Abraham, outside the Supreme Court on June 24, 2022. Hannah Beier for NBC News

Donations to abortion funds and clinics have helped enable travel for people like Nekia. Last year, abortion funds provided more than $36 million in aid to those seeking abortions, according to the National Network of Abortion Funds.At the same time, a new public spotlight on abortion has helped advocates promote resources for people seeking them.

“One of the positive consequences of the horrific decision overturning Roe, was that people became more aware of their rights, even as these rights were taken

away," said Julie Kay, executive director of the Abortion Coalition for Telemedicine Access.

However, leaders of abortion funds and networks said donations have waned significantly in the last year, raising questions about whether interstate travel for abortions will continue at the same pace in the future.

"To be able to remain open to serve multiple people, we have to put limitations on the amount that we support per client," said Stephanie Loraine Piñeiro, executive director of the Florida Access Network, an abortion fund.

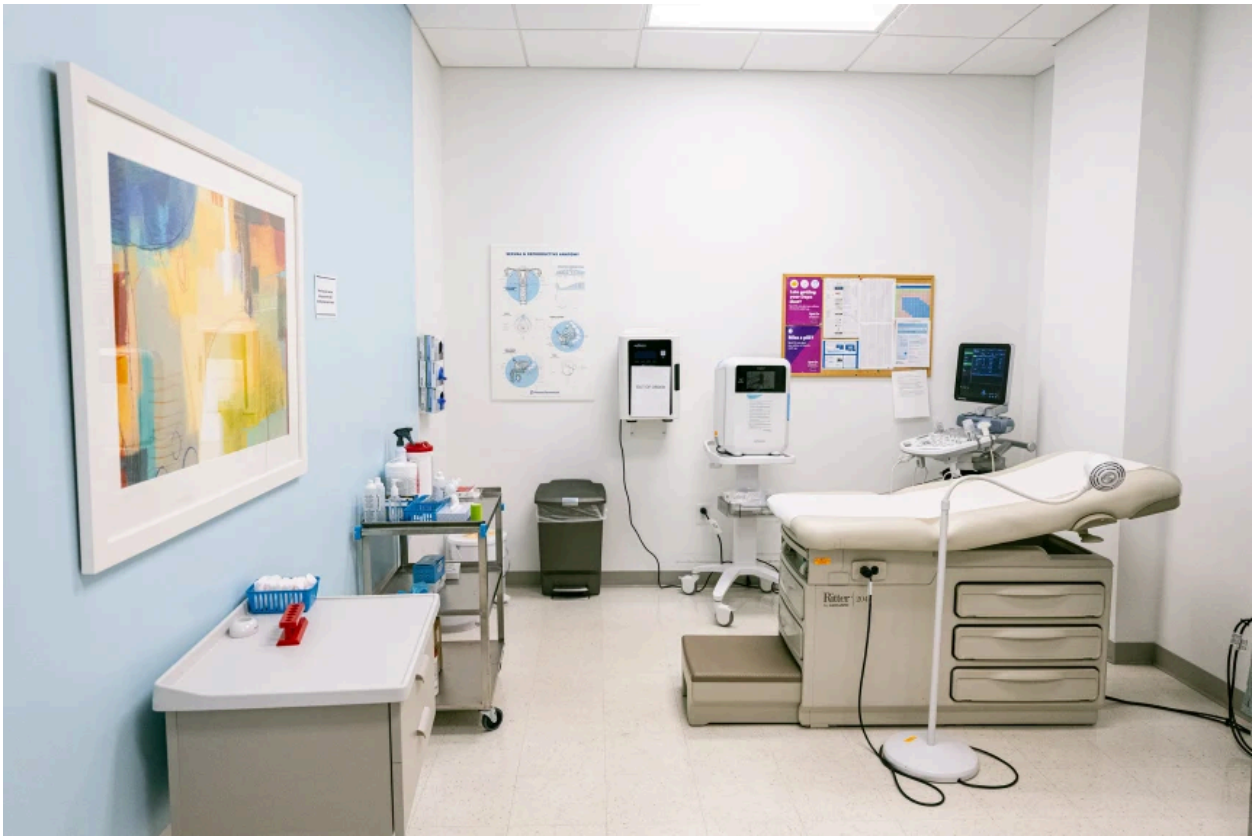
What the data hides

The nationwide rise in abortions can obscure the reality that some people who want abortions still can't get them – particularly low-income women of color.

Dr. Amy Whitaker, chief medical officer at a Planned Parenthood clinic in Flossmoor, Illinois, said the Dobbs decision has made it significantly harder for patients to reach her.

"Even the ones who make it to care, they just have had to go through so much more," she said.

Indeed, the waiting room at her clinic was packed on a Friday morning in September. Many patients travel long distances to get there from states with abortion restrictions – the clinic estimates they make up about 22% of its abortion patients.



An examination room at a Planned Parenthood Health Center in Louisville, Ky., in 2022. Jon Cherry / Getty Images file

Data isn't available on how many unwanted pregnancies have been carried to term since the Dobbs decision, but an April study found that abortion bans had resulted in a 2% average increase in births in the states that implemented them."You can clearly see that there is a little bit of an increase in childbearing relative to the nonban states," said Sarah Miller, a health economist at the University of Michigan.

Whitaker is known for her exuberance among her staff – sometimes dancing in the hallways between appointments – but the aftermath of the Dobbs decision has changed her demeanor.

"When you know your patients are struggling and suffering, it affects your day to day," she said. "I cry more often. I'm just so sad."

What comes next?

Advocates on both sides of the abortion rights issue don't think a federal ban is likely after Trump takes office, but they anticipate that the new administration could restrict abortion in other ways. One avenue they described is for the FDA

to rescind the licensing of mifepristone or roll back the changes that expanded its access.

“My expectation would be that his FDA would re-evaluate the Biden FDA’s decision to authorize mail-order abortion and determine that it was unlawful and dangerous to do so,” said Erik Baptist, senior counsel for the Alliance Defending Freedom, an anti-abortion legal group.

The attorneys general of Idaho, Kansas and Missouri also filed a lawsuit last month challenging the FDA actions that expanded mifepristone access. The case was filed in a federal court in Texas where the sole judge, Matthew Kacsmaryk, is a Trump appointee.

— Misoprostol tablets at a family planning clinic. Anna Moneymaker / Getty Images file

Kacsmaryk previously ruled in favor of abortion opponents who challenged mifepristone, but the Supreme Court said the plaintiffs lacked standing to sue. Reproductive rights lawyers said that this time, Trump’s Justice Department could choose not to appeal if Kacsmaryk sides with the attorneys general.Additionally, the lawyers raised the possibility that the next attorney

general could try to enforce the Comstock Act, an 1873 law that prohibits mailing and receiving "obscene" materials and those designed or intended to procure an abortion.

The Center for Reproductive Rights and the American Civil Liberties Union – the legal groups behind several major abortion rights cases – said they have strategies to counter any future changes to FDA rules or enforcement of the Comstock Act. The Center last year also filed a lawsuit challenging some remaining FDA restrictions on mifepristone. Planned Parenthood, meanwhile, has said it will continue fighting for abortion rights via state ballot measures.

To Gomperts, whose organizations have managed to skirt abortion restrictions around the world for decades, the election results aren't cause for panic.

"Whatever happens, people will get their abortion pills no matter what," she said. "I don't think that is ever going to go away."

This article was produced in collaboration with the USC Annenberg Center for Health Journalism's 2024 National Fellowship Fund for Reporting on Child Well-being.

Aria Bendix

Aria Bendix is the breaking health reporter for NBC News Digital.


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EXHIBIT 14

Complaint, *Rodriguez v. Coeytaux*,
No. 3:25-cv-00225, (S.D. Tex. July 20, 2025)

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

Jerry Rodriguez, on behalf of himself and others similarly situated, Plaintiff, v. **Remy Coeytaux**, Defendant.	Case No. 3:25-cv-225

COMPLAINT

Under the law of Texas, a person who assists a pregnant woman in obtaining a self-managed abortion commits the crime of murder and can be sued for wrongful death. *See* Texas Penal Code § 1.07; *id.* at § 19.02; *id.* at § 19.06 (murder statute); Tex. Civ. Prac. & Rem. Code § 71.001 *et seq.* (wrongful-death statute). It is also a state jail felony for anyone other than a Texas-licensed physician to provide an abortion-inducing drug for the purpose of inducing an abortion. *See* Tex. Health & Safety Code § 171.063(a); Tex. Health & Safety Code § 171.065(a).

In violation of these and many other laws, defendant Remy Coeytaux mailed abortion-inducing drugs into Texas that were used to murder Jerry Rodriguez's unborn child. Mr. Rodriguez sues to recover damages from Coeytaux for this wrongful death. Mr. Rodriguez also seeks an injunction to stop Coeytaux from distributing abortion-inducing drugs in violation of state or federal law.

JURISDICTION AND VENUE

1. The Court has subject-matter jurisdiction under 28 U.S.C. § 1332, as the parties are diverse and the amount in controversy exceeds $75,000.00.

2. The Court has personal jurisdiction over defendant Coeytaux because he purposefully and knowingly mailed abortion-inducing drugs into Texas in violation of state law, and Mr. Rodriguez's claim arises out of those minimum contacts with the forum state.

3. Venue is proper in this district and division because a substantial part of the events giving rise to the claims occurred in Galveston County. *See* 28 U.S.C. § 1391(b)(2). Venue is additionally proper because each of the defendants resides in Galveston County. *See* 28 U.S.C. § 1391(b)(1).

PARTIES

4. Plaintiff Jerry Rodriguez is a citizen of Texas.

5. Defendant Remy Coeytaux is a citizen of California, where he operates a solo medical practice.

STATEMENT OF FACTS

6. Plaintiff Jerry Rodriguez began dating Kendal Garza in June of 2024.

7. In July of 2024, Kendal became pregnant with Mr. Rodriguez's child.

8. Although Kendal was happy about the pregnancy and told Mr. Rodrigez that she planned to give birth, her estranged husband (Adam Garza) was displeased and wanted the baby murdered. Kendal had legally separated from Adam years before she started dating Mr. Rodriguez but had not yet divorced him.

9. On September 16, 2024, at 9:10 P.M. central time, Adam Garza ordered abortion-inducing drugs online from Coeytaux with the intent of using them to murder Mr. Rodriguez's unborn child. A Venmo receipt confirming Adam's purchase of the drugs from Coeytaux is attached as Exhibit 1. The receipt indicates that the drugs were purchased for $150.00 from "Remy Coeytaux MD PC" and describes the purchase as "'Aed axes Kendal Garza.'" The first two words ("Aed axes") are homophones

for "Aid Access," an organization that illegally ships abortion-inducing drugs into jurisdictions where abortion has been outlawed. Payment was made with a Visa Debit card whose last four digits are 1012. The payment was remitted to a Venmo account with the handle "@RemyCoeytaux."

10. After receiving this order, Coeytaux shipped the abortion-inducing drugs to Adam Garza's house in Galveston County, Texas.

11. On September 19, 2024, Kendal Garza used the drugs that Adam had purchased from Coeytaux to kill the unborn child that she conceived with Mr. Rodriguez. Kendal told Mr. Rodriguez that Adam Garza provided her with the abortion drugs, and that both Adam and her mother (Kim Crawford Williams) pressured her to kill the baby with the drugs obtained from Coeytaux. Kendal ingested the abortion-inducing drugs and killed Mr. Rodriguez's unborn child at Ms. Williams's house in Galveston County. Kendal was more than 10 weeks pregnant when she took the pills.

12. In late October 2024, Kendal became pregnant for a second time with Mr. Rodriguez's child. Kendal was again happy about the pregnancy and told Mr. Rodrigez that she planned to give birth to their child, a son. On January 18, 2025, Kendal and Mr. Rodriguez together went to a doctor's appointment and were provided with sonograms of the baby boy, which are attached as Exhibit 2.

13. But later in January Kendal killed Mr. Rodriguez's unborn son with abortion pills that were illegally obtained and provided by Adam Garza. This time Kendal took the abortion-inducing drugs at Adam's house in Galveston County. Kendal proceeded with this self-managed abortion even though she was nearly three months pregnant and even though Mr. Rodriguez pleaded with her not to do it. After the abortion, Kendal texted Mr. Rodriguez and told him that she had to cut the baby boy's umbilical cord and bury him (although she did not say where).

14. In May of 2025, Kendal became pregnant for a third time with Mr. Rodriguez's child. She is now two months pregnant. Mr. Rodriguez fears that Adam Garza

will again pressure Kendal to kill his unborn child and obtain abortion pills from Coeytaux to commit the murder.

CLAIM FOR RELIEF NO. 1 — WRONGFUL DEATH

15. The wrongful-death statute allows surviving parents to sue those who cause the death of an unborn child by a wrongful act, neglect, carelessness, unskillfulness, or default. *See* Tex. Civ. Prac. & Rem. Code § 71.002(b) ("A person is liable for damages arising from an injury that causes an individual's death if the injury was caused by the person's or his agent's or servant's wrongful act, neglect, carelessness, unskillfulness, or default."); Tex. Civ. Prac. & Rem. Code § 71.001(4) ("'Individual' includes an unborn child at every stage of gestation from fertilization until birth.").

16. Defendant Coeytaux caused the death of Mr. Rodriguez's unborn child through his wrongful acts, which violated the law in each the following respects:

17. Section 171.063(a)(1) of the Texas Health and Safety Code prohibits anyone other than a Texas-licensed physician from providing abortion-inducing drugs to a pregnant woman for the purpose of inducing an abortion. *See* Tex. Health & Safety Code § 171.063(a) ("A person may not knowingly provide an abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion in the pregnant woman or enabling another person to induce an abortion in the pregnant woman unless: (1) the person who provides the abortion-inducing drug is a physician"). A violation of section 171.063(a)(1) is a state jail felony. *See* Tex. Health & Safety Code § 171.065(a). Coeytaux is not a Texas-licensed physician, so he violated section 171.063(a)(1) by knowingly sending abortion-inducing drugs into Texas, which he knew would be provided to a pregnant woman for the purpose of inducing an abortion. Coeytaux is also criminally responsible for Adam Garza's violations of section 171.063(a)(1) because Coeytaux knowingly aided Adam's provision of abortion-inducing drugs to a pregnant woman. *See* Tex. Penal Code § 7.02.

18. Section 171.063(a)(2) of the Texas Health and Safety Code prohibits individuals from providing abortion-inducing drugs to a pregnant woman for the purpose of abortion unless they comply with the protocols in subchapter D of chapter 171 of the Texas Health and Safety Code. *See* Tex. Health & Safety Code § 171.063(a) ("A person may not knowingly provide an abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion in the pregnant woman or enabling another person to induce an abortion in the pregnant woman unless: . . . (2) the provision of the abortion-inducing drug satisfies the protocol authorized by this subchapter"). A violation of section 171.063(a)(2) is a state jail felony. *See* Tex. Health & Safety Code § 171.065(a). Coeytaux violated section 171.063(a)(2) by knowingly sending abortion-inducing drugs into Texas, which he knew would be provided to a pregnant woman for the purpose of inducing an abortion. Coeytaux is also criminally responsible for Adam Garza's violations of section 171.063(a)(2) because he knowingly aided Adam's provision of abortion-inducing drugs to a pregnant woman. *See* Tex. Penal Code § 7.02.

19. Section 171.0631 of the Texas Health and Safety Code prohibits any person from providing abortion-inducing drugs to a pregnant woman without complying with the informed-consent requirements of subchapter B of chapter 171 of the Texas Health and Safety Code, which include a mandatory ultrasound. *See* Tex. Health & Safety Code § 171.0631 ("A person may not provide an abortion-inducing drug to a pregnant woman without satisfying the applicable informed consent requirements of Subchapter B."). A violation of section 171.0631 is a state jail felony. *See* Tex. Health & Safety Code § 171.065(a). Coeytaux violated section 171.0631 by knowingly sending abortion-inducing drugs into Texas, which he knew would be provided to a pregnant woman for the purpose of inducing an abortion. Coeytaux is also criminally responsible for Adam Garza's violations of section 171.0631 because he knowingly

aided Adam's provision of abortion-inducing drugs to a pregnant woman. *See* Tex. Penal Code § 7.02.

20. Section 171.003 of the Texas Health and Safety Code prohibits anyone other than a Texas-licensed physician to perform abortions. *See* Tex. Health & Safety Code § 171.003 ("An abortion may be performed only by a physician licensed to practice medicine in this state."). Coeytaux is not a Texas-licensed physician, and he performed an abortion in violation of section 171.003 by arranging for the delivery and provision of the abortion pills that Kendal Garza used in her self-managed abortion. Coeytaux further violated section 171.003 by knowingly aiding an illegal self-managed abortion in Texas. *See* Tex. Penal Code § 7.02.

21. Section 171.011 of the Texas Health and Safety Code prohibits any person from performing an abortion without complying with the informed-consent requirements of subchapter B of chapter 171 of the Texas Health and Safety Code, which include a mandatory ultrasound. *See* Tex. Health & Safety Code § 171.011 ("A person may not perform an abortion without the voluntary and informed consent of the woman on whom the abortion is to be performed."). Coeytaux performed an abortion in violation of section 171.011 by arranging for the delivery and provision of the abortion pills that Kendal Garza used in her self-managed abortion, which did not comply with the mandatory ultrasound and other statutory informed-consent requirements in Texas law. Coeytaux has further violated section 171.011 by aiding an illegal self-managed abortion in Texas without complying with the mandatory ultrasound and other statutory informed-consent requirements.

22. Chapter 245 of the Texas Health and Safety Code requires abortions in Texas to be performed in licensed abortion facilities (subject to exceptions not applicable here). *See* Tex. Health & Safety Code § 245.002(2) ("'Abortion facility' means a place where abortions are performed."); *id.* at § 245.003(a) ("Except as provided by Section 245.004, a person may not establish or operate an abortion facility in this state

without an appropriate license issued under this chapter."). Coeytaux violated chapter 245 of the Texas Health and Safety Code by performing and assisting an abortion that took place outside a licensed abortion facility.

23. Federal law imposes criminal liability on any person who:

a. Knowingly uses the mails for the mailing, carriage, or delivery of abortion-inducing drugs;

b. Knowingly uses any express company, common carrier, or interactive computer service for carriage of abortion-inducing drugs in interstate or foreign commerce; or

c. Knowingly takes or receives abortion-inducing drugs from an express company, a common carrier, or an interactive computer service.

18 U.S.C. §§ 1461–1462. Coeytaux violated these federal criminal laws by sending abortion-inducing drugs into Texas with the intent of aiding an illegal abortion.

24. Articles 4512.1–4512.6 of the Texas Revised Civil Statutes make abortion a felony criminal offense unless the life of the mother is endangered. Violations of articles 4512.1–4512.6 are punishable by two to five years imprisonment. Coeytaux violated articles 4512.1–4512.6 by performing or assisting an abortion in Texas that was not needed to save the life of the mother.

25. Section 170A.002 of the Texas Health and Safety Code also makes abortion a felony criminal offense unless the abortion is performed to avert the risk of death or a serious risk of substantial impairment of a major bodily function. *See* Tex. Health & Safety Code § 170A.002. Violations of section 170A.002 are punishable by five to 99 years imprisonment. *See* Tex. Penal Code § 12.32. Coeytaux violated section 170A.002 by performing or assisting an abortion in Texas that was not needed to avert the risk of death or a serious risk of substantial impairment of a major bodily function.

26. Assisting a self-managed abortion in Texas is an act of murder. *See* Texas Penal Code § 1.07; *id.* at § 19.02; *id.* at § 19.06 (murder statute). Although Kendal

Garza cannot be charged with murder for her role in killing her unborn child,[1] her immunity does not shield Coeytaux from liability for aiding or abetting or directly participating in the murder. *See* Tex. Penal Code § 7.03 ("In a prosecution in which an actor's criminal responsibility is based on the conduct of another, the actor may be convicted on proof of commission of the offense and that he was a party to its commission, and it is no defense: (1) that the actor belongs to a class of persons that by definition of the offense is legally incapable of committing the offense in an individual capacity; or (2) that the person for whose conduct the actor is criminally responsible has been acquitted, has not been prosecuted or convicted, has been convicted of a different offense or of a different type or class of offense, or is immune from prosecution."). Coeytaux directly committed murder under section 19.02(b)(1) because he "intentionally and knowingly caused the death" of Mr. Rodriguez's unborn child by delivering abortion pills that he knew would be used in an illegal self-managed abortion. *See* Tex. Penal Code § 19.02(b) ("A person commits an offense if he: (1) intentionally or knowingly causes the death of an individual"). And Coeytaux directly committed murder under section 19.02(b)(2) because he "intended to cause serious bodily injury and committed an act clearly dangerous to human life that caused the death" of Mr. Rodriguez's unborn child. *See* Tex. Penal Code § 19.02(b) ("A person commits an offense if he: . . . (2) intends to cause serious bodily injury and commits an act clearly dangerous to human life that causes the death of an individual").

27. Coeytaux is also guilty of felony murder under section 19.02(b)(3) of the Texas Penal Code. Coeytaux's shipment of abortion pills to Adam Garza was a felony. *See* Tex. Health & Safety Code § 171.063(a); Tex. Health & Safety Code § 171.065(a); 18 U.S.C. §§ 1461–1462. Coeytaux also committed an act "clearly

1. *See* Texas Penal Code § 19.06 ("This chapter does not apply to the death of an unborn child if the conduct charged is: (1) conduct committed by the mother of the unborn child").

dangerous to human life that causes the death of an individual." Tex. Penal Code § 19.02(b)(3); Texas Penal Code § 1.07 (defining "individual" to include "an unborn child at every stage of gestation from fertilization until birth."). Coeytaux therefore committed felony murder under section 19.02(b)(3).

28. The manufacturers and distributors of the abortion pills that Kendal used are jointly and severally liable for the wrongful death of Mr. Rodriguez's unborn child, and they will be added as defendants once identified. The manufacturer and distributors caused the death of Mr. Rodriguez's unborn child through a "wrongful act" because they violated 18 U.S.C. §§ 1461–1462, which imposes federal criminal liability on anyone who knowingly sends or receives abortion pills through the mail or by using any express company, common carrier, or interactive computer service.

29. None of the exceptions in Texas's wrongful-death statute shield the defendants (or the manufacturers and distributors of the abortion pills) from liability. Sections 71.003(c)(2) and (c)(4) of the Texas Civil Practice and Remedies Code are inapplicable because assisting a self-managed abortion is not a "lawful medical procedure," nor is it a "lawful medical or health care practice or procedure." Section 71.003(c)(3) is inapplicable because the abortion pills were not dispensed or administered "in accordance with law." Coeytaux is therefore liable under section 71.003 and must pay damages to Mr. Rodriguez for murdering his unborn child.

30. Mr. Rodriguez seeks damages in excess of $75,000.00, the minimum amount in controversy required for diversity jurisdiction. *See* 28 U.S.C. § 1332(a).

CLAIM FOR RELIEF NO. 2 — INJUNCTION

31. Mr. Rodriguez has standing to seek injunctive relief against Coeytaux because Kendal Garza is again pregnant with his unborn child, and there is a substantial risk that Adam Garza will obtain abortion pills illegally from Coeytaux and provide those to Kendal. *See TransUnion LLC v. Ramirez*, 594 U.S. 413, 435–36 (2021)

("[A] person exposed to a risk of future harm may pursue forward-looking, injunctive relief to prevent the harm from occurring"). This risk is fairly traceable to the allegedly unlawful conduct of Coeytaux, who continues to send abortion pills into Texas in violation of state and federal law, and it will be redressed by an injunction that restrains Coeytaux from illegally distributing abortion-inducing drugs.

32. Mr. Rodriguez seeks this injunction on behalf of a class of all current and future fathers of unborn children in the United States. *See* Fed. R. Civ. P. 23(b)(2).

DEMAND FOR RELIEF

33. Mr. Rodriguez respectfully requests that the court:

a. certify the class described in paragraph 32;

b. order Coeytaux to pay nominal, compensatory, and punitive damages to for the wrongful death of Mr. Rodriguez's unborn child;

c. permanently enjoin Coeytaux from distributing abortion-inducing drugs in violation of state or federal law, including 18 U.S.C. §§ 1461–1462;

d. award Mr. Rodriguez court costs and attorneys' fees; and

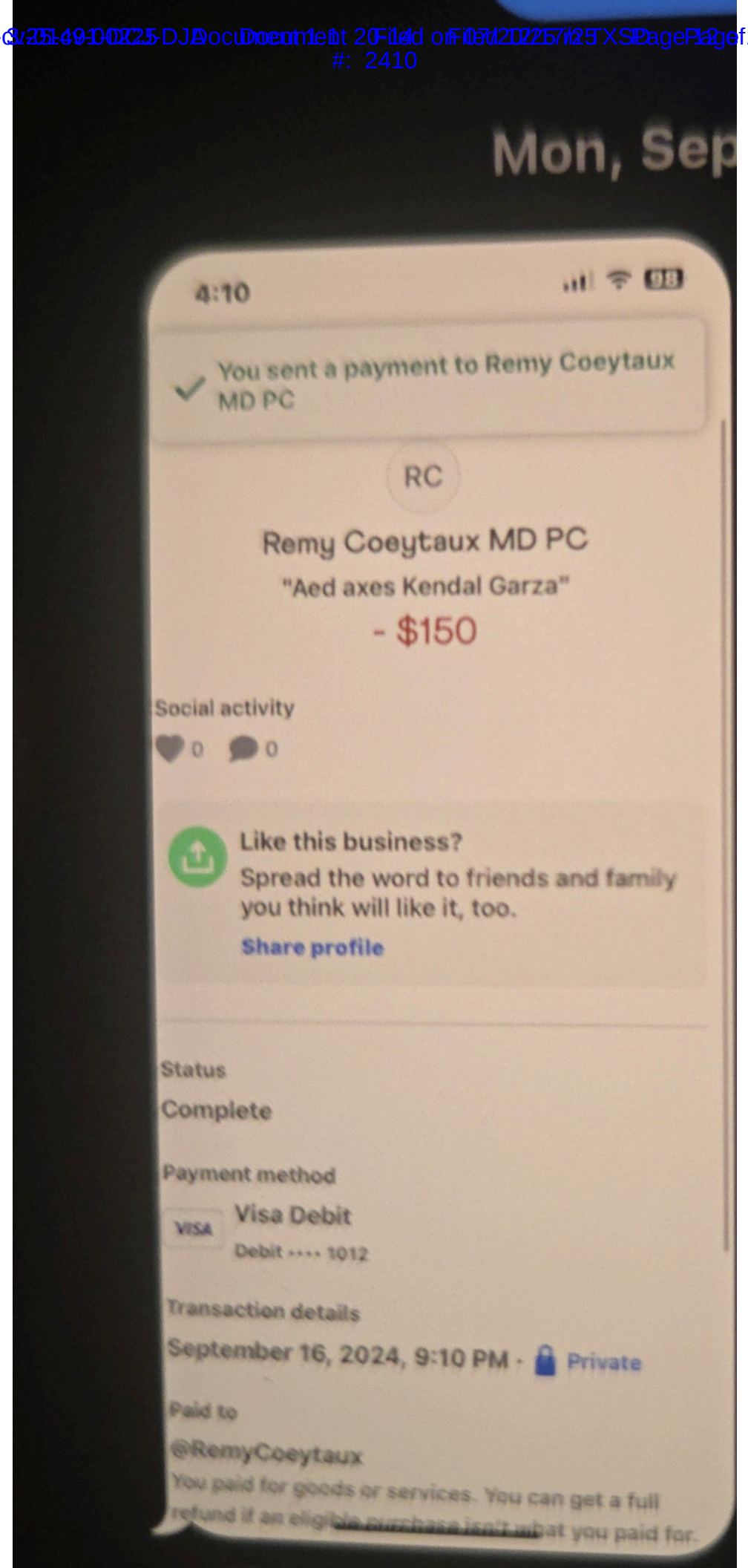
e. grant all other relief that the Court deems just, proper, or equitable.

Respectfully submitted.

/s/ Jonathan F. Mitchell
JONATHAN F. MITCHELL
Attorney in Charge
Texas Bar No. 24075463
S.D. Tex. Bar No. 1133287
Mitchell Law PLLC
111 Congress Avenue, Suite 400
Austin, Texas 78701
(512) 686-3940 (phone)
(512) 686-3941 (fax)
jonathan@mitchell.law

Counsel for Plaintiff and Proposed Class

Dated: July 20, 2025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Like this business?
Spread the word to friends and family you think will like it, too.
Share profile
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Complete
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Transaction details
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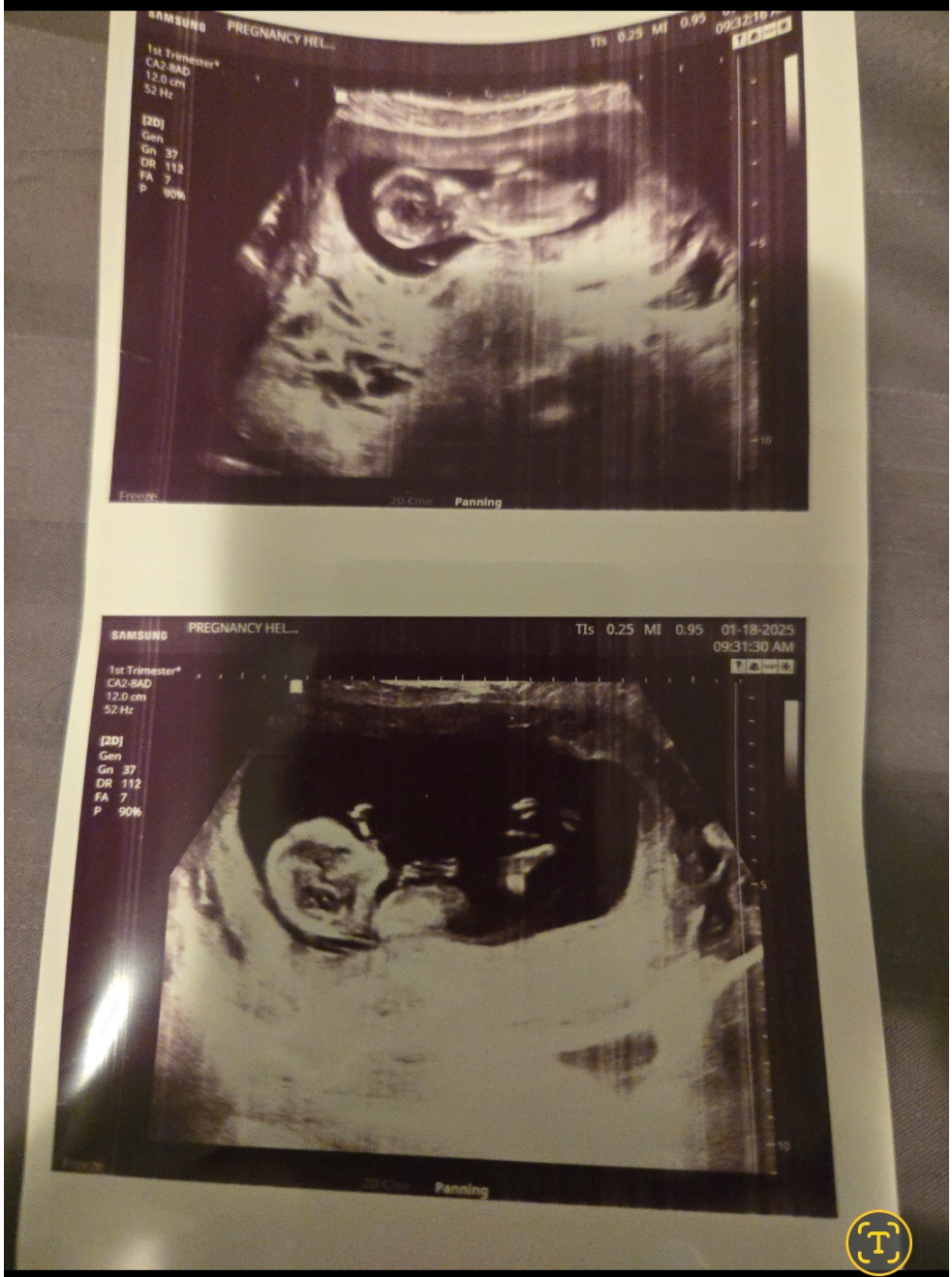
Paid to
@RemyCoeytaux
You paid for goods or services. You can get a full refund if an eligible purchase isn't what you paid for.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PREGNANCY HEL...
TIs 0.25 MI 0.95
1st Trimester*
CA2-BAD
12.0 cm
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Gen
Gn 37
DR 112
FA 7
P 90%
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2D Cine
Panning
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PREGNANCY HEL...
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Gn 37
DR 112
FA 7
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Freeze
2D Cine
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EXHIBIT 15

Notice of Cease and Desist
from Ken Paxton, Att'y Gen. of Tex., to Remy Coeytaux
(Aug. 14, 2025)

KEN PAXTON
ATTORNEY GENERAL OF TEXAS

August 14, 2025

Via Certified Mail
7010 1060 0000 3703 4653

Remy Coeytaux
7765 Bodega Avenue
Sebastopo, California 95472

RE: Notice of Cease and Desist

Dear Mr. Coeytaux:

The Office of the Attorney General (OAG) has become aware that you have shipped abortion drugs into the State of Texas in violation of both state and federal laws. This letter serves as your notice to immediately **CEASE AND DESIST** this illegal activity.

You have been named in a recently filed lawsuit as having shipped abortion pills into the State of Texas via your affiliation with Aid Access. In *Rodriguez v. Coeytaux*, the plaintiff alleges that the abortion pills which caused the death of two preborn children were obtained from Aid Access via an order prescribed by you. Complaint at 2–3, No. 3:25-cv-00225 (S.D. Tex. Jul. 20, 2025), ECF No. 1.

This conduct violates multiple state and federal laws.

Performing, inducing, or attempting an abortion is prohibited in the State of Texas by the Human Life Protection Act, except for the rare circumstance when a woman has a life-threatening physical condition that poses a risk of death or serious physical impairment unless an abortion is performed. Tex. Health & Safety Code § 170A.002(a), (b); *see also* Texas Revised Civil Statutes Art. 4512.1–4512.6. Any person who "knowingly engages in conduct that aids or abets the performance or inducement of an abortion" is civilly and criminally liable for violating Texas's abortion laws. Tex. Health & Safety Code § 171.208; Tex. Health & Safety Code § 170A.004, Tex. Pen. Code § 7.02.

Furthermore, Texas law also specifically prohibits:

- Anyone not licensed as a physician in Texas from performing an abortion, Tex. Health & Safety Code §§ 171.003; 171.063(a)(1),
- A person from providing abortion-inducing drugs to a pregnant woman, Tex. Health & Safety Code § 171.063(a)(2);

- A manufacturer, supplier, physician, or any other person from providing to a patient any abortion-inducing drug by courier, delivery, or mail service, Tex. Health & Safety Code § 171.063(b-1).

In addition, the Comstock Act of 1873 prohibits the carriage in interstate commerce of "any drug, medicine, article, or thing designed, adapted or intended for producing abortion." 18 U.S.C. § 1462. Similarly, it prohibits the mailing of any "article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion." *Id.* § 1461.

Based on the allegations in *Rodriguez v. Coeytaux*, it appears that you are in violation of multiple state and federal laws. The Attorney General of Texas accordingly demands that you **IMMEDIATELY CEASE AND DESIST** from mailing abortion-inducing drugs into the State of Texas.

If you refuse to comply, a formal investigation will be initiated, and the Attorney General may bring a lawsuit against you for injunctive relief and civil penalties. If the Attorney General finds that you have committed violations of Texas's abortion laws, you will be prosecuted to the fullest extent permitted by law. The Attorney General may seek civil penalties for violations of the Human Life Protection Act of **not less than $100,000 per violation**.

Notify the OAG of the steps you have taken to remedy your violations of Texas law within 14 days of the date of this letter. Your response should be in writing and addressed to the address below. Alternatively, you may provide your response by email to Amy.Hilton@oag.texas.gov.

Thank you for your attention to this matter.

Sincerely,

/s/ Amy Snow Hilton

AMY SNOW HILTON
Chief, Healthcare Program Enforcement Division
KATHERINE PITCHER
Assistant Attorney General
Office of the Attorney General of Texas
Healthcare Program Enforcement Division
P.O. Box 12548, Capitol Station
Austin, Texas 78711-2548
Phone: (512) 936-1709
Amy.Hilton@oag.texas.gov
Katherine.Pitcher@oag.texas.gov
COUNSEL FOR STATE OF TEXAS

EXHIBIT 16

FDA, REMS Single Shared System for Mifepristone 200MG (May 2021)

Initial Shared System REMS approval: 04/2019
Most Recent Modification: 05/2021

Mifepristone Tablets, 200 mg

Progestin Antagonist

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

SINGLE SHARED SYSTEM FOR MIFEPRISTONE 200MG

I. GOAL

The goal of the REMS for mifepristone is to mitigate the risk of serious complications associated with mifepristone by:

a) Requiring healthcare providers who prescribe mifepristone to be certified in the Mifepristone REMS Program.

b) Ensuring that mifepristone is only dispensed in certain healthcare settings by or under the supervision of a certified prescriber.

c) Informing patients about the risk of serious complications associated with mifepristone.

II. REMS ELEMENTS

A. Elements to Assure Safe Use

1. Healthcare providers who prescribe mifepristone must be specially certified.
   a. To become specially certified to prescribe mifepristone, healthcare providers must:
      i. Review the Prescribing Information for mifepristone.
      ii. Complete a *Prescriber Agreement Form*. By signing a *Prescriber Agreement Form*, prescribers agree that:
         1) They have the following qualifications:
            a) Ability to assess the duration of pregnancy accurately
            b) Ability to diagnose ectopic pregnancies
            c) Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
         2) They will follow the guidelines for use of mifepristone (see b.i-v below).
   b. As a condition of certification, healthcare providers must follow the guidelines for use of mifepristone described below:
      i. Review the *Patient Agreement Form* with the patient and fully explain the risks of the mifepristone treatment regimen. Answer any questions the patient may have prior to receiving mifepristone.

ii. Sign the *Patient Agreement Form* and obtain the Patient's signature on the *Form*

iii. Provide the patient with a copy of the *Patient Agreement Form* and Medication Guide.

iv. Place the signed *Patient Agreement Form* in the patient's medical record.

v. Record the serial number from each package of mifepristone in each patient's record.

vi. Report any deaths to the Mifepristone Sponsor that provided the mifepristone, identifying the patient by a non- identifiable reference and the serial number from each package of mifepristone.

c. Mifepristone Sponsors must:

i. Ensure that healthcare providers who prescribe their mifepristone are specially certified in accordance with the requirements described above and de-certify healthcare providers who do not maintain compliance with certification requirements

ii. Provide the Prescribing Information and their *Prescriber Agreement Form* to healthcare providers who inquire about how to become certified.

The following materials are part of the REMS and are appended:

- *Prescriber Agreement Form for Danco Laboratories, LLC*
- *Prescriber Agreement Form for GenBioPro, Inc.*
- *Patient Agreement Form*

2. Mifepristone must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.

a. Mifepristone Sponsors must:

i. Ensure that their mifepristone is available to be dispensed to patients only in clinics, medical offices and hospitals by or under the supervision of a certified prescriber.

ii. Ensure that their mifepristone is not distributed to or dispensed through retail pharmacies or other settings not described above.

3. Mifepristone must be dispensed to patients with evidence or other documentation of safe use conditions.

a. The patient must sign a *Patient Agreement Form* indicating that the patient has:

i. Received, read and been provided a copy of the *Patient Agreement Form*.

ii. Received counseling from the prescriber regarding the risk of serious complications associated with mifepristone.

B. Implementation System

1. Mifepristone Sponsors must ensure that their mifepristone is only distributed to clinics, medical offices and hospitals by or under the supervision of a certified prescriber by:

a. Ensuring that distributors who distribute their mifepristone comply with the program requirements for distributors. The distributors must:

i. Put processes and procedures in place to:

a. Complete the healthcare provider certification process upon receipt of a Prescriber Agreement Form.

b. Notify healthcare providers when they have been certified by the Mifepristone REMS Program.

c. Ship mifepristone only to clinics, medical offices, and hospitals identified by certified prescribers in their signed *Prescriber Agreement Form*.

d. Not ship mifepristone to prescribers who become de-certified from the Mifepristone REMS Program.

e. Provide the Prescribing Information and their Prescriber Agreement Form to healthcare providers who (1) attempt to order mifepristone and are not yet certified, or (2) inquire about how to become certified.

ii. Put processes and procedures in place to maintain a distribution system that is secure, confidential and follows all processes and procedures, including those for storage, handling, shipping, tracking package serial numbers, proof of delivery and controlled returns of mifepristone.

iii. Train all relevant staff on the Mifepristone REMS Program requirements.

iv. Comply with audits by Mifepristone Sponsors, FDA or a third party acting on behalf of Mifepristone Sponsors or FDA to ensure that all processes and procedures are in place and are being followed for the Mifepristone REMS Program. In addition, distributors must maintain appropriate documentation and make it available for audits.

b. Ensuring that distributors maintain secure and confidential distribution records of all shipments of mifepristone.

2. Mifepristone Sponsors must monitor their distribution data to ensure compliance with the REMS Program.

3. Mifepristone Sponsors must audit their new distributors within 90 calendar days after the distributor is authorized to ensure that all processes and procedures are in place and functioning to support the requirements of the Mifepristone REMS Program. Mifepristone Sponsors will take steps to address their distributor compliance if noncompliance is identified.

4. Mifepristone Sponsors must take reasonable steps to improve implementation of and compliance with the requirements of the Mifepristone REMS Program based on monitoring and assessment of the Mifepristone REMS Program.

5. Mifepristone Sponsors must report to FDA any death associated with mifepristone whether or not considered drug-related, as soon as possible but no later than 15 calendar days from the initial receipt of the information by the applicant. This requirement does not affect the applicants other reporting and follow-up requirements under FDA regulations.

C. Timetable for Submission of Assessments

The NDA Sponsor must submit REMS assessments to FDA one year from the date of the initial approval of the REMS (04/11/2019) and every three years thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. The NDA Sponsor must submit each assessment so that it will be received by the FDA on or before the due date.

PRESCRIBER AGREEMENT FORM

Mifeprex® (Mifepristone) Tablets, 200 mg

Mifeprex* (Mifepristone) Tablets, 200 mg, is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Please see Prescribing Information and Medication Guide for complete safety information.

To set up your account to receive Mifeprex, you must:
1. complete, 2. sign, and 3. fax page 2 of this form to the distributor.

If you will be ordering for more than one facility, you will need to list each facility on your order form before the first order will be shipped to the facility.

Prescriber Agreement: By signing page 2 of this form, you agree that you meet the qualifications below and will follow the guidelines for use. You also understand that if you do not follow the guidelines, the distributor may stop shipping Mifeprex to you.

Mifeprex must be provided by or under the supervision of a healthcare provider who prescribes and meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the Prescribing Information of Mifeprex. The Prescribing Information is available by calling our toll free number, 1-877-4 Early Option (1-877-432-7596), or logging on to our website, www.earlyoptionpill.com.

In addition to meeting these qualifications, you also agree to follow these guidelines for use:

- Review the Patient Agreement Form with the patient and fully explain the risks of the Mifeprex treatment regimen. Answer any questions the patient may have prior to receiving Mifeprex.
- Sign and obtain the patient's signature on the Patient Agreement Form.
- Provide the patient with a copy of the Patient Agreement Form and the Medication Guide.
- Place the signed Patient Agreement Form in the patient's medical record.
- Record the serial number from each package of Mifeprex in each patient's record.
- Report deaths to Danco Laboratories, identifying the patient by a non-identifiable patient reference and the serial number from each package of Mifeprex.

ACCOUNT SETUP MIFEPREX® (Mifepristone) Tablets, 200 mg; NDC 64875-001-01

TO SET UP YOUR ACCOUNT:

1. Read the Prescriber Agreement on page 1 of this form.
2. Complete and sign this form.
3. Fax this page to the Danco distributor at 1-866-227-3343. Your account information will be kept strictly confidential.
4. The distributor will call to finalize your account setup and take your initial order.
5. Subsequent orders may be phoned or faxed and are usually shipped within 24 hours.

Mifeprex® (Mifepristone) Tablets, 200 mg
THE ORIGINAL EARLY OPTION PILL

BILLING INFORMATION

Bill to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

SHIPPING INFORMATION ☐ *Check if same as above*

Ship to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

ADDITIONAL SITE LOCATIONS *I will also be prescribing Mifeprex* at these additional locations:*

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

(Any additional sites may be listed on an attached sheet of paper.)

REQUEST ADDITIONAL MATERIALS

☐ **Medication Guides** ☐ **State Abortion Guides** ☐ **Patient Brochures** ☐ **Patient Agreement Form**

ESTABLISHING YOUR ACCOUNT *(required only with first order)*

Each facility purchasing Mifeprex must be included on this form (*see additional site locations box above*) before the distributor can ship the product to the facility.

By signing below, you agree that you meet the qualifications and that you will follow the guidelines for use on page 1 of the Prescriber Agreement.

Print Name _____ Signature _____

Medical License # _____ Date _____

FAX THIS COMPLETED FORM TO THE AUTHORIZED DISTRIBUTOR. FAX: 1-866-227-3343

Please fax any questions to the above number or call 1-800-848-6142.

*MIFEPREX is a registered trademark of Danco Laboratories, LLC.

Reference ID: 3909592

Reference ID: 4795916

Mifepristone Tablets, 200 mg, is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Please see Prescribing Information and Medication Guide for complete safety information.

To set up your account to receive mifepristone, you must:
1. complete, 2. sign and 3. fax page 2 of this form to the distributor.

If you will be ordering for more than one facility, you will need to list each facility on your order form before the first order will be shipped to the facility.

Prescriber Agreement: By signing page 2 of this form, you agree that you meet the qualifications below and will follow the guidelines for use. You also understand that if you do not follow the guidelines, the distributor may stop shipping mifepristone to you.

Mifepristone must be provided by or under the supervision of a healthcare provider who prescribes and meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the Prescribing Information for mifepristone. The Prescribing Information is available by calling our toll free number, 1-855-MIFE-INFO (1-855-643-3463), or logging on to our website, www.MifeInfo.com.

In addition to having these qualifications, you also agree to follow these guidelines for use:

- Review the Patient Agreement Form with the patient and fully explain the risks of the mifepristone treatment regimen. Answer any questions the patient may have prior to receiving mifepristone.
- Sign and obtain the patient's signature on the Patient Agreement Form.
- Provide the patient with a copy of the Patient Agreement Form and the Medication Guide.
- Place the signed Patient Agreement Form in the patient's medical record.
- Record the serial number from each package of mifepristone in each patient's record.
- Report deaths to GenBioPro, identifying the patient by a non-identifiable patient reference and the serial number from each package of mifepristone.

ACCOUNT SETUP

Mifepristone Tablets, 200 mg; NDC 43393-001-01

TO SET UP YOUR ACCOUNT:

1. **Read the Prescriber Agreement on Page 1 of this form.**
2. **Complete and sign this form.**
3. **Fax this page to the GenBioPro distributor at 1-877-239-8036.**
   Your account information will be kept strictly confidential.
4. **The distributor will call to finalize your account setup and take your initial order.**
5. **Subsequent orders may be phoned or faxed and are usually shipped within 24 hours**

BILLING INFORMATION

Bill to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

SHIPPING INFORMATION ☐ *Check if same as above*

Ship to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

ADDITIONAL SITE LOCATIONS *I will also be prescribing mifepristone at these additional locations:*

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

(Any additional sites may be listed on an attached sheet of paper)

REQUEST ADDITIONAL MATERIALS

☐ **Medication Guides** ☐ **State Abortion Guides** ☐ **Patient Brochures** ☐ **Patient Agreement Form**

ESTABLISHING YOUR ACCOUNT *(required only with first order)*

Each facility purchasing mifepristone tablets must be included on this form (*see additional site locations box above*) before the distributor can ship the product to the facility.
By signing below, you agree that you meet the qualifications and that you will follow the guidelines for use on page 1 of the Prescriber Agreement.

Print Name _____ Signature _____

Medical License # _____ Date _____

FAX THIS COMPLETED FORM TO THE AUTHORIZED DISTRIBUTOR. FAX: 1-877-239-8036

Please fax any questions to the above number or call 1-877-239-8036

PATIENT AGREEMENT FORM Mifepristone Tablets, 200mg

Healthcare Providers: *Counsel the patient on the risks of mifepristone. Both you and the patient must sign this form.*

Patient Agreement:

1. I have decided to take mifepristone and misoprostol to end my pregnancy and will follow my provider's advice about when to take each drug and what to do in an emergency.
2. I understand:
   a. I will take mifepristone on Day 1.
   b. My provider will either give me or prescribe for me the misoprostol tablets, which I will take 24 to 48 hours after I take mifepristone.
3. My healthcare provider has talked with me about the risks, including:
   - heavy bleeding
   - infection
   - ectopic pregnancy (a pregnancy outside the womb)
4. I will contact the clinic/office right away if in the days after treatment I have:
   - a fever of 100.4°F or higher that lasts for more than four hours
   - severe stomach area (abdominal) pain
   - heavy bleeding (soaking through two thick full-size sanitary pads per hour for two hours in a row)
   - stomach pain or discomfort, or I am "feeling sick," including weakness, nausea, vomiting, or diarrhea, more than 24 hours after taking misoprostol
5. My healthcare provider has told me that these symptoms could require emergency care. If I cannot reach the clinic or office right away, my healthcare provider has told me who to call and what to do.
6. I should follow up with my healthcare provider about 7 to 14 days after I take mifepristone to be sure that my pregnancy has ended and that I am well.
7. I know that, in some cases, the treatment will not work. This happens in about 2 to 7 out of 100 women who use this treatment. If my pregnancy continues after treatment with mifepristone and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy.
8. If I need a surgical procedure because the medicines did not end my pregnancy or to stop heavy bleeding, my healthcare provider has told me whether they will do the procedure or refer me to another healthcare provider who will.
9. I have the MEDICATION GUIDE for mifepristone. I will take it with me if I visit an emergency room or a healthcare provider who did not give me mifepristone so that they will understand that I am having a medical abortion with mifepristone.
10. My healthcare provider has answered all my questions.

Patient Signature: _____ **Patient Name** (print): _____ **Date**: _____

The patient signed the PATIENT AGREEMENT in my presence after I counseled the patient and answered all questions. I have given the patient the MEDICATION GUIDE for mifepristone.

Provider's Signature: _____ **Name of Provider** (print): _____ **Date**: _____

After the patient and the provider sign this PATIENT AGREEMENT, give 1 copy to the patient before the patient leaves the office and put 1 copy in the medical record.

EXHIBIT 17

REMS Compliance Program,
FDA (Sep. 22, 2022)

← Risk Evaluation and Mitigation Strategies | REMS

REMS Compliance Program

FDA conducts inspections to evaluate compliance with risk evaluation and mitigation strategies (REMS) requirements to ensure the drug's health benefits outweigh the risks for patients. Inspections are prioritized using a risk-based approach.

The agency will take action if issues found during the REMS inspections are not promptly and adequately corrected. Failure to comply with REMS requirements may result in enforcement action such as product seizure, injunction or civil money penalties.

FDA also reviews REMS assessment reports to evaluate compliance with legal and regulatory requirements. The agency takes appropriate regulatory action for noncompliance, which may include warning letters or untitled letters, to address serious safety concerns and mitigate risks to patients.

Additional resources

- REMS@fda
- REMS compliance program guide
- Webinar: Risk Evaluation and Mitigation Strategies (REMS) compliance program
- Webinar: Postmarketing drug safety and inspection readiness

Guidances

- FDA's application of statutory factors in determining when a REMS is necessary
- Development of a shared system REMS
- REMS assessment: Planning and reporting
- Format and content of REMS
- Medication guides – Distribution requirements and inclusion in REMS
- REMS: Modifications and revisions
- Providing regulatory submissions in electronic format – Content of the REMS document using Structured Product Labeling
- Use of a drug master file for shared system REMS submissions
- Waivers of the single shared system REMS requirement
- Survey methodologies to assess REMS goals that relate to knowledge
- Policy for certain REMS requirements during the COVID-19 public health emergency

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09/22/2022

Regulated Product(s)

Drugs

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EXHIBIT 18

Declaration of John Voltz, M.D.
(Nov. 17, 2025)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*.	Case No.: 6:25-cv-01491-DCJ-DJA Judge David C. Joseph Magistrate Judge David J. Ayo

DECLARATION OF DR. JOHN VOLTZ

I, John Voltz, M.D., a citizen of the United States of America and a resident of the State of Louisiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge. I am fully competent to make this declaration. If called to testify, I could and would testify competently to these facts.
2. I am a board-certified obstetrician and gynecologist. I graduated from Menard High School in Alexandria in 2006. I attended Louisiana State University, graduating in Civil Engineering in 2010. After graduation, I served as a full-time uniform Patrol Deputy in the East Baton Rouge Sheriff's Office.
3. I received my medical degree from Louisiana State University Health Sciences Center–Shreveport in 2018 and completed my residency at Saint Louis University in 2022. I returned home to Louisiana after residency, and I have practiced medicine in Louisiana since 2022.
4. I am a practicing obstetrician and gynecologist with admitting privileges at a large local general medical center in Lafayette, Louisiana.
5. I provide general OB/GYN care. I provide, among other things, labor and delivery care, prenatal care, preventative care, preconception counseling, and minimally invasive and vaginal gynecologic surgery, along with treatment for abnormal bleeding, infertility, pelvic pain, and menopause. I specialize in multiple births, high-risk pregnancies, and vaginal births after a cesarean section. I deliver approximately 300 babies per year.
6. I am on call as an emergency room consultant at the local general medical center in Lafayette.
7. Seventy percent of my patients are enrolled in Medicaid and pay for my services through Medicaid.

8. I have witnessed firsthand how the abortion drug mifepristone has hurt women in Louisiana.

9. I have treated a Louisiana patient who suffered complications after taking mifepristone in 2025.

10. The patient I treated was at five weeks gestation. I performed a dilation and curettage procedure due to an incomplete abortion and severe bleeding. This patient was on private insurance.

11. I presume this patient received the mifepristone by out-of-state mail because abortion drugs are illegal in Louisiana and no in-state provider could dispense the drugs in Louisiana.

12. Another patient—pregnant in her teenage years—came to my office with her mother. Her mother wanted her to take abortion drugs. At one of her ultrasound appointments, the unborn baby was no longer in the uterus. She had taken prescription mifepristone and misoprostol. The patient and her mother showed me the envelope the drugs were mailed in—with a New York sending address.

Executed this 17TH day of NOVEMBER 2025.

By _____
John Voltz, M.D.

EXHIBIT 19

Declaration of Kathleen Richard, LMSW
(Nov. 12, 2025)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*.	Case No.: 6:25-cv-01491-DCJ-DJA Judge David C. Joseph Magistrate Judge David J. Ayo

DECLARATION OF KATHLEEN RICHARD

I, Kathleen Richard, a citizen of the United States of America and a resident of the State of Louisiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge. I am fully competent to make this declaration. If called to testify, I could and would testify competently to these facts.
2. I am the executive director of Life Choices of North Central Louisiana, a pregnancy resource center in Ruston, Louisiana. I have witnessed how the abortion drug mifepristone has hurt women in Louisiana. Life Choices encounters women considering abortion and women who have had an abortion—including by mifepristone.
3. Since 2022, Life Choices has regularly encountered women who took abortion drugs, who have received abortion drugs in the mail, and many who sought treatment for complications after taking them.
4. These women are either Louisiana residents or college students living in Louisiana.
5. In 2024, Life Choices encountered approximately 75 abortion-minded or undecided pregnant women. At least 65% of these women had abortion drugs in their possession or knew where they could get the drugs. Most of the women received their drugs from out-of-state providers through the mail. They identified Plan C (https://www.plancpills.org/) as the most common source for the drugs.
6. Women call Life Choices once or twice per month asking for a follow-up ultrasound after taking mifepristone.
7. Life Choices has encountered several Louisiana women who suffered mifepristone complications. Many of them come to Life Choices to share their experiences and seek counseling. For example, mifepristone complications sent one woman to the

emergency room and hospital with excessive bleeding after she passed out. Her abortion-drug provider told her not to tell doctors that she had taken mifepristone. She is on Medicaid.

8. A second woman took mifepristone, suffered from excessive bleeding, and had two ultrasounds at her healthcare provider confirm that products of conception were in her uterus. She is on Medicaid.

9. A third woman who took mifepristone passed out at home but did not go to the emergency room.

Executed this 12 day of Nov, 2025.

By Kathleen B Richard, LMSW
Kathleen Richard, LMSW

EXHIBIT 20

Declaration of Kathleen Willis, M.D.
(Dec. 15, 2025)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants.*	Case No.: 6:25-cv-01491-DCJ-DJA Judge David C. Joseph Magistrate Judge David J. Ayo

DECLARATION OF KATHLEEN WILLIS, M.D.

Pursuant to 28 U.S.C. § 1746, I, Kathleen Willis, M.D., affirm under penalty of perjury:

1. I am over the age of 18, have personal knowledge of the matters set forth herein, and am competent to make this Declaration.

2. I serve as the Associate Medical Director for Louisiana Medicaid in the Louisiana Department of Health ("LDH"). I completed medical school and residency at LSU School of Medicine in New Orleans and served as Chief Resident of the Internal Medicine Residency Program in my final year. I am board certified in Internal Medicine and a lifetime member of the AOA Honor Medical Society. I've been a physician for 26 years with over 20 years of leadership experience in healthcare delivery, quality improvement, and healthcare administration.

3. I help oversee the clinical and medical policy aspects of the State's Medicaid program, which runs through LDH's Bureau of Health Services Financing. My responsibilities include developing and evaluating medical policies to ensure they are evidence-based and cost-effective; reviewing coverage decisions, prior authorization criteria, and clinical guidelines used by Medicaid and its Managed Care Organizations ("MCOs"); providing clinical guidance to Medicaid leadership on

program operations, benefits, and emerging health issues; and collaborating with MCOs, providers, and LDH divisions to align care standards and address medical or utilization concerns.

4. Louisiana Medicaid provides healthcare coverage to eligible low-income individuals as part of a cooperative effort between the State of Louisiana and the federal government, who jointly fund the program. Louisiana Medicaid covers a broad set of services, including hospital and physician care, prescriptions, labs and imaging, long-term care, behavioral health, and more.

5. Louisiana Medicaid also covers emergency services at *any* hospital emergency room ("ER"), whether or not the hospital is in the patient's Medicaid MCO network. We follow federal Medicaid laws that require LDH to cover emergency care. When an individual covered by Medicaid goes to an ER, the hospital will run the patient's Medicaid ID through the State's electronic eligibility system, but emergency care cannot be delayed while the provider is verifying coverage. As part of Medicaid coverage, and under EMTALA, the ER must, at a minimum, perform a medical screening exam, stabilize the patient, and provide any necessary treatment. Louisiana Medicaid and all MCOs prohibit prior authorization for emergency services: The hospital treats the patient first, bills later. After treatment, the hospital submits the claim to the appropriate MCO (or Medicaid fee-for-service, if applicable), and payment goes directly from the plan/Medicaid to the provider. The patient typically has no copay, unless a small copay applies under their specific plan.

6. In 2021, the Department of Health and Human Services estimated that the average cost of a Medicaid-covered ER visit was $600—a number we can safely assume has increased in the past 4 years due to inflation and rising healthcare costs generally. In June 2023, approximately 2 million people were enrolled in Louisiana Medicaid. As of June 2024, the number dropped slightly to just over 1.6 million, as States across the country have seen the overall number of Medicaid enrollees decline from the extreme uptick during the COVID-19 pandemic. However, the decline has stopped: As of June 2025, the number of Louisiana Medicaid enrollees remained around 1.6 million, a number that

surpasses pre-pandemic data. As of January 1, 2023 (the most recent data of its kind available), 534,294 women from ages 15 to 44 were enrolled and 538,139 women from ages 15 to 44 were recipients.[1]

7. The FY 2025 Medicaid budget for Louisiana is about $21.2 billion, with the State covering about 25% of these costs and the federal government covering the remainder. Louisiana Medicaid accounts for roughly 38% of the State's total budget. In FY 2023 (the most recent data available), Louisiana Medicaid cost the federal and State government a combined $16.6 billion.[2]

8. I am familiar with the U.S. Food & Drug Administration's 2023 Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone. I understand that women who ingest mifepristone may end up in the emergency room to treat and remedy side effects of the drug.

9. When such women are covered by Medicaid, the resulting services are paid for by the State (and the federal government) under Medicaid. The patients often do not absorb the costs.

10. These emergent situations and associated Medicaid costs will continue to be a problem in Louisiana because of mifepristone that is being mailed into Louisiana.

11. In 2025, a Louisiana woman on Medicaid—Jane Doe #1—received emergency medical care at a Louisiana regional medical center after ingesting FDA-approved mifepristone that she received in the mail from AidAccess.org. She delivered a dead fetus in the emergency room. As a result of the services rendered by the Louisiana medical center to Jane Doe #1, the total cost billed to Medicaid was over $17,500 and the total amount paid was over $4,500.

12. In 2025, another Louisiana woman covered by Medicaid—Jane Doe #2—ingested FDA-approved abortion drugs in Louisiana that she received in the mail from AidAccess.org. Two

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[1] The information in this paragraph comes from *Louisiana Medicaid 2023 Annual Report*, Louisiana Department of Health, p.26 (https://ldh.la.gov/assets/medicaid/AnnualReports/MedicaidAnnualReport2023.pdf) (last visited Dec. 9, 2025).

[2] *See, e.g.*, *Medicaid Enrollment Declines*, PAR Louisiana (July 28, 2025) (https://parlouisiana.org/wp-content/uploads/2025/07/Medicaid-Enrollment-Declines2.pdf).

days later, she arrived at a Louisiana emergency room with severe abdominal pain and delivered her baby alive. The baby needed emergency treatment and a prolonged hospitalization. As a result of this emergency room visit, the total cost billed to Medicaid for the mother's treatment was over $24,000 and the total amount paid was over $7,500. The total cost billed for the baby's treatment was over $299,500 and the total amount paid was over $80,000.

13. These women are just two examples of many women believed to have suffered adverse health consequences requiring emergency medical care at Louisiana's hospitals, paid for by Louisiana Medicaid, as a result of ingesting FDA-approved supplies of mifepristone.

14. These figures almost certainly understate the true harm, owing to incomplete hospital reporting, miscoding or false reporting of complications as "miscarriages," and concealed shipments. Louisiana Medicaid covers miscarriage treatment and reimburses for miscarriage treatment and care.[3]

15. Because the amount of mifepristone illegally prescribed and shipped to Louisiana women is unlimited and increasing, there is no doubt that the number of adverse health consequences requiring emergency medical care in Louisiana hospitals will only increase as well, as will the associated costs borne by Louisiana Medicaid.

Executed in Baton Rouge, Louisiana, this 15th day of December, 2025.

Kathleen Willis, M.D.

Kathleen Willis, M.D.

[3] *See LaMOMS*, Louisiana Department of Health (https://ldh.la.gov/medicaid/lamoms) (last visited Dec. 9, 2025).