UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE FAMILY PLANNING ASSOCIATION OF MAINE D/B/A MAINE FAMILY PLANNING, on behalf of itself, its staff, and its patients, *et al.*,	Case No. 1:19-cv-00100-LEW
Plaintiffs,	
v.	**REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO AMEND PRELIMINARY INJUNCTION ORDER, OR IN THE ALTERNATIVE FOR INJUNCTION PENDING APPEAL**
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,	
Defendants.	

Defendants do not dispute that Maine Family Planning will be forced to shutter at least eleven clinics as a result of the Rule absent an alternative funding source, nor that the New Law will not remediate that harm.[1] In the face of these undisputed facts, the Court's findings to the contrary were manifestly erroneous and the Order denying Plaintiffs' Motion for Preliminary Injunction should be amended accordingly.

Defendants contend that the Order's mischaracterization of the New Law is immaterial, Opp. at 2-3—but, that is belied by the Court's own statement that the New Law "has serious implications for Plaintiffs' preliminary injunction showing" and by the Court's incorrect assumption that "[g]iven it is now lawful for APRNs to provide abortion services, Plaintiffs'

[1] The "Rule" refers to *Compliance with Statutory Program Integrity Requirements*, 84 Fed. Reg. 7714-01 (March 4, 2019), which is Defendants' regulation for the Title X program that is challenged in this case. The "New Law" refers to a recent-enacted Maine law, An Act to Authorize Certain Health Care Professionals to Perform Abortion, P.L. 2019, ch. 262 §§ 1596 to 159-A, which was signed into law on June 10, 2019. All terms in this Reply should be read according to the definitions set forth in Plaintiffs' opening memorandum, ECF No. 78-1.

portrayal of driving burdens is not calibrated to existing conditions." Order at 25 n.23. Indeed, evidence of such burdens—including clinic closures that would exponentially increase driving distances for *both* family planning and abortion services in Maine—was central to Plaintiffs' Motion for Preliminary Injunction. That evidence was a key aspect of Plaintiffs' claim that the Rule violates patients' Fifth Amendment right to pre-viability abortion, as well as to Plaintiffs' demonstrations of strong reliance interests, irreparable harm, and a balance of equities that weighs heavily in favor of injunctive relief.

Accordingly, the Court should reconsider its denial of Plaintiffs' Motion for Preliminary Injunction in order to correctly characterize and assess the impact of the New Law. Alternatively, Plaintiffs respectfully request an injunction of the Rule pending resolution of Plaintiffs' forthcoming appeal to the First Circuit.

ARGUMENT

I. The Court Should Amend the Order to Correctly Address the Limited Impact of the New Law and Grant Plaintiffs' Requested Injunction Accordingly

Defendants' Opposition confirms that the Order should be amended under Federal Rule of Civil Procedure 59, in order to correctly account for the limited impact of the New Law and to grant a preliminary injunction against enforcement of the Rule.

Defendants effectively concede that the New Law does not alleviate harms from the Rule. They do not dispute that the Rule will force MFP out of the Title X program. Nor do they dispute that the Rule will cause MFP to lose 39% of its current annual funding for family planning services or that MFP will ultimately need to close 11-15 of its directly-controlled sites absent an alternative long-term funding source. Hill Decl. ¶ 26. Defendants have offered no evidence to counter these facts, nor do they even suggest that the New Law will alleviate these

harms in any way. Defendants even acknowledge that the New Law *should have* been irrelevant to the Court's analysis of the Rule's impacts. *See* Opp. at 1-2.[2]

In light of these concessions, Defendants' argument that "Plaintiffs do not identify any error—let alone any manifest error—in the Court's treatment of the new Maine law," Opp. at 3, is shown to be unfounded. The Court incorrectly concluded that because of the New Law, MFP would be able to keep more sites open under the Rule than initially anticipated, which would minimize driving distances. Order at 25 n.23. In actuality, however, the New Law does not decrease the Rule's impacts on clinics in Maine. Pls.' Mem. at 4. This is manifest error.

Alternatively, Defendants argue that—regardless of whether the Court erred in its assessment of the New Law—that analysis was immaterial to the Order. On the contrary, the Court made explicit its view that the New Law "has serious implications for Plaintiffs' preliminary injunction showing," Order at 25 n.23, and repeatedly invoked the New Law as a basis to disregard Plaintiffs' evidence. For example, the Court incorrectly concluded that the New Law "undermines many of the assumptions upon which Plaintiffs' motion for preliminary injunction relies," *id.* at 14 n.13, by making it more likely that MFP could keep a wider set of clinics open, *id.* at 23 n.20, and thereby minimize travel burdens for patients under the Rule, *id.* at 25 n.23. *See also id.* at 26 (speculating that the factual underpinnings of an expert declaration on driving burdens could be modified "in light of the recent amendment to Maine abortion law"). Nor does it matter, as Defendants suggest, that the New Law was not cited in "the 'Discussion' section of [the Court's] opinion." Opp. at 2-3. As recognized by the First Circuit, a conclusion may be central to a court's decision regardless of whether it is an explicit holding and even if it is

[2] Defendants only defense of the Court's conclusions about the New Law is a lone statement, presented without citation or any explication, that the Court's conclusions were "eminently reasonable." Opp. at 3.

otherwise identified as dicta. *See Arcam Pharm. Corp. v. Faria*, 513 F.3d 1, 3 (1st Cir. 2007). The significance of a conclusion to a legal opinion is not limited to form but also arises from substance—*i.e.*, what "portions of the opinion" are "necessary to the result?" *Id.* That standard clearly is met here, where the Court itself explained that its conclusions about the New Law had "serious implications" for its decision. Order at 14 n.13.

Under these circumstances—where certain of the Court's conclusions are flatly inconsistent with the evidence presented—Plaintiffs' motion does not "rehash old arguments about abortion in Maine that the Court has already extensively considered," Opp. at 3, but rather seeks for the Court to reconsider its legal conclusions on a corrected factual record. Indeed, issues associated with passage of the New Law could not have been addressed in Plaintiffs' prior briefings because, as Defendants note, the New Law was passed only after briefing on Plaintiffs' preliminary injunction motion had already concluded. *See* Opp. at 2. Thus, it falls squarely within the Court's purview to correct the record and reconsider its decision now. *See Nat'l Metal Finishing Co. v. Barclays American/Commercial, Inc.*, 899 F.2d 119, 124-25 (1st Cir. 1990) (a party may not rehash arguments already made or already available on a Rule 59(e) motion, but beyond that, the trial court has broad discretion in "reviewing her own findings for manifest error").

Accordingly, the Court should amend the Order with respect to the impact of the New Law and reconsider the Motion for Preliminary Injunction in accordance with the corrected record.

II. The Court Should Enjoin the Rule Pending Appeal

Plaintiffs have briefed extensively the reasons why (1) they are likely to succeed on the merits; (2) they will suffer irreparable harm absent an injunction; (3) Defendants will not be

substantially harmed by an injunction; and (4) an injunction is in the public interest. *See* ECF Nos. 17-1, 63, 78-1. Plaintiffs maintain that injunctive relief should be granted pending appeal for those same reasons.

Indeed, the need for an injunction pending appeal has been further reinforced by new guidance from HHS with respect to the timelines on which the Rule will be enforced. On July 20, 2019, HHS (through Defendant Diane Foley) sent grantees an email with guidance materials, including "Grantee Guidance—Documenting Compliance with the 2019 Title X Final Rule Compliance with Statutory Program Integrity Requirements." *See* Ex. 1, Declaration of Emily B. Nestler, Exs. A & B.[3] The guidance documents reaffirmed that "compliance with the 2019 Final Rule, except for the physical separation requirement, was required as of July 15, 2019" and threatened "enforcement actions" against those failing to make "good-faith efforts to comply with the Final Rule." *Id*. HHS further directed all grantees to provide written "assurance[s]" with respect to compliance on August 19, 2019 and again on September 18, 2019. *Id*. Absent injunctive relief before August 19, therefore, MFP will need to leave the Title X program due to the intolerable ethical and financial restrictions the Rule will impose. Supp. Hill Decl. ¶ 12. An appeal to the First Circuit is highly unlikely to be resolved by that date, and thus a preliminary injunction is necessary in the interim to prevent drastic changes to the status quo and resulting irreparable harms.

Absent an injunction pending appeal, Plaintiffs will suffer immediate and irreparable harm before the First Circuit even has had a chance to consider the important constitutional and public health issues at stake in this case. Accordingly, Plaintiffs' motion should be granted.

[3] Defendant Foley's July 20 email also included two other attachments: (1) "Compliance with Statutory Program Integrity Requirements," *id.*, Ex. C; and (2) "Fact Sheet: Final Title X Rule Detailing Family Planning Grant Program," *id.*, Ex. D.

CONCLUSION

For the foregoing reasons and the reasons set forth in Plaintiffs' Memorandum in Support of their Motion, Plaintiffs respectfully request that this Court amend the Decision and Order on Motion for Preliminary Injunction, or alternatively grant injunctive relief until the First Circuit has decided the forthcoming appeal.

Dated: July 29, 2019

Respectfully submitted,
/s/ Richard L. O'Meara_____

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**Admitted Pro Hac Vice*

EXHIBIT 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE FAMILY PLANNING ASSOCIATION OF MAINE D/B/A MAINE FAMILY PLANNING, on behalf of itself, its staff, and its patients, *et al.*,	Case No. 1:19-cv-00100-LEW
Plaintiffs,	
v.	**DECLARATION OF EMILY B. NESTLER IN SUPPORT OF PLAINTIFFS' REPLY IN SUPPORT OF MOTION TO AMEND PRELIMINARY INJUNCTION ORDER, OR IN THE ALTERNATIVE FOR INJUNCTION PENDING APPEAL**
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,	
Defendants.	

I, Emily B. Nestler, declare as follows:

1: I am an attorney at the Center for Reproductive Rights and am counsel of record for Plaintiffs the Family Planning Association of Maine d/b/a Maine Family Planning and Dr. J. Doe in this action.

2: In support of Plaintiffs' Reply in Support of their Motion to Amend Preliminary Injunction Order, or in the Alternative for Injunction Pending Appeal, I hereby testify as follows:

3: Attached hereto as Exhibit A is a true and correct copy of an e-mail sent by Diane Foley to George Hill and others on July 20, 2019, with the subject "Guidance for grantees re: compliance with Title X regulation" (the "Foley Email").

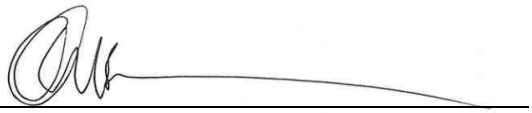
4: Attached hereto as Exhibit B is a true and correct copy of a document that was attached to the Foley email, entitled "Grantee Guidance—Documenting Compliance with the 2019 Title X Final Rule Compliance with Statutory Program Integrity Requirements."

5: Attached hereto as Exhibit C is a true and correct copy of a document that was attached to the Foley email, entitled "Compliance with Statutory Program Integrity Requirements."

6: Attached hereto as Exhibit D is a true and correct copy of a document that was attached to the Foley email, entitled "Fact Sheet: Final Title X Rule Detailing Family Planning Grant Program."

7: I declare under penalty of perjury that the foregoing is true and correct.

Executed this 29th day of July, 2019 at New York, NY.



Emily B. Nestler

Exhibit A

From: "Foley, Diane (HHS/OASH)" <Diane.Foley@hhs.gov>
Date: July 20, 2019 at 9:34:47 PM EDT
To: OS - OPHS OPA <OPA.OS@hhs.gov>, OS - OPHS OAH <OS-OPHSOAH@ees.hhs.gov>, "Witt, Jacki" <WittJ@umkc.edu>, Reesa Webb <reesa_webb@jsi.com>
Subject: Guidance for grantees re: compliance with Title X regulation

Good evening,

It was good to meet and talk with so many of you at the conference this week. We trust your travel home was uneventful. As promised, please find attached the guidance for next steps in compliance with the new regulation as well as the announcement that was sent out on Monday. We have also attached a fact sheet that will answer many of the questions that were addressed this week. We are working on answers to the questions that were unanswered and further guidance will be forthcoming.

As always, OPA is committed to working with all of our grantees to come into compliance with the new regulations. The FPNTC website will have the documents available to help with this process and we are available to help you communicate these changes with your subrecipients. Please let us know how we can further assist you with this process.

Diane Foley MD, FAAP
Deputy Assistant Secretary
Office of Population Affairs
Office of the Assistant Secretary for Health/HHS
Phone: 240-453-2826 (office-direct)
202-868-9400 (cell)

Exhibit B

Grantee Guidance – Documenting Compliance with the 2019 Title X Final Rule *Compliance with Statutory Program Integrity Requirements*

As stated earlier this week (attached), compliance with the 2019 Final Rule, except for the physical separation requirement, was required as of July 15, 2019.

In the past, the U.S. Department of Health and Human Services, Office of Population Affairs (OPA), has exercised enforcement discretion in appropriate circumstances. Given the circumstances surrounding the implementation of the Final Rule, OPA does not intend to bring enforcement actions against Title X recipients that are making, and continue to make, good-faith efforts to comply with the Final Rule. OPA is committed to working with grantees to assist them in coming into compliance with the requirements of the Final Rule.

As part of those good-faith efforts, OPA expects the following:

1. **Assurance and Action Plan Documenting Steps to Come Into Compliance – Due by August 19, 2019**

   - A written assurance stating that the project does not provide abortion and does not include abortion as a method of family planning.
   - An action plan describing the steps that they will take to come into compliance with all aspects of the Final Rule.
   - The action plan must be submitted as a Grant Note in Grantsolutions, and an email must be sent to the Project Officer indicating that the plan has been submitted.
   - <u>The expectation is that grantees will begin to implement the actions stated in their action plans immediately.</u>
   - If there are any questions or concerns about a grantee's action plan, the OPA project officer will notify the grantee within 2 weeks.

2. **Statement and Supporting Evidence with Compliance Requirements – Due by September 18, 2019**

   - A written statement, signed by the Project Director and Authorized Official stating that the grant project is in compliance with the 2019 Title X Final Rule, except for the physical separation requirements.
   - For each requirement, the grantee must (1) describe the steps that were taken to ensure that the grant project is in compliance and (2) provide any relevant documentation needed for OPA to verify compliance (e.g., copies of revised policies, plan for monitoring subrecipients, staff training plan).
   - The written statement and any supporting documentation must be submitted as a Grant Note in Grantsolutions. An email must be sent to the Project Officer indicating that the statement and supporting documentation have been submitted.

3. Statement and Supporting Evidence for Physical Separation between Title X Services and Abortion Services – Due by March 4, 2020

- A written statement, signed by the Program Director and Authorized Official, stating that the grant project is in compliance with the requirement for physical separation between Title X services and abortion services as stated in the 2019 Title X Final Rule.

- For the requirement for physical separation between Title X services and abortion services, the grantee must (1) describe the steps that were taken to ensure that the grant project is in compliance and (2) provide any relevant documentation needed for OPA to verify compliance (e.g., copies of revised policies, plan for monitoring subrecipients, staff training plan).

- The written statement and any supporting documentation must be submitted as a Grant Note in Grantsolutions. An email must be sent to the Project Officer indicating that the statement and supporting documentation have been submitted.

If the grantee believes that it cannot meet the deadlines listed above, it must submit a request for an extension as a Grant Note in Grantsolutions, along with an explanation or documentation of the need for the extension. The compliance deadline may be extended only if such extension is necessary to promote the orderly and effective implementation of the Title X project and the Final Rule. An email must be sent to the Project Officer indicating that the request has been submitted.

Exhibit C

Compliance With Statutory Program Integrity Requirements

Earlier this year, district courts in California, Maryland, Oregon, and Washington issued preliminary injunctions preventing the U.S. Department of Health and Human Services (HHS) from enforcing the March 2019 Final Rule, titled *Compliance With Statutory Program Integrity Requirements*. Among other things, the Final Rule ensures statutory compliance with Section 1008 of Title X, which states, "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning."

Motions panels in the Fourth and Ninth Circuit stayed the injunctions, but plaintiffs in the Ninth Circuit cases filed motions for an administrative stay of the Ninth Circuit's stay order. On July 11, 2019, an *en banc* panel of the Ninth Circuit denied those requests for an administrative stay and made clear that the order staying the injunctions remained in effect. By denying those motions, the *en banc* Ninth Circuit—along with the Fourth Circuit and a federal district court in Maine that recently denied another motion for a preliminary injunction—has made clear that HHS may begin enforcing the Final Rule. Consistent with those rulings, HHS shall now require compliance with the Final Rule.

As set forth in the Final Rule, compliance with the physical-separation requirements in the Final Rule is required by March 4, 2020, and the Rule's grant-application criteria will apply to the next competitive- or continuation-award applications due after July 2, 2019. The Final Rule established that compliance with the financial-separation requirements, and certain reporting, assurance, and provision-of-service requirements, was required by July 2, 2019. All other requirements were set to take effect on May 3, 2019, but the prior preliminary injunctions, including two nationwide injunctions, prevented HHS from enforcing those provisions.

Compliance with the requirements of the Final Rule, except for the physical-separation requirements, is therefore required as of Monday, July 15, 2019.

Exhibit D

Fact Sheet: Final Title X Rule Detailing Family Planning Grant Program

Earlier this year, the Department of Health and Human Services issued a final rule to revise the regulations governing the Title X family planning program. This week, the Office of Population Affairs informed the Title X grantees that compliance with the requirements of the Final Rule, except for the physical separation requirements, was required as of Monday, July 15, 2019.

Background

Title X is the only federal program dedicated solely to the provision of family planning and related preventive services tailored to individual needs, with priority given to those from low income families. Established in 1970, the program provides funding "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)."[1]

Pursuant to Congressional mandate, family participation is to be encouraged, particularly in services involving adolescents. And, from the start, Congress was clear that Title X funds cannot be used to support abortion. [2]

The Title X program serves approximately 4 million clients every year. This final rule ensures that grants and contracts awarded under this program fully comply with the statutory program integrity requirements, thereby fulfilling the purpose of Title X, so that more women and men can receive services that help them consider and achieve both their short-term and long-term family planning needs.

Summary of Final Rule

[1] PHS Act § 1001(a), 42 U.S.C. § 300(a).

[2] "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." PHS Act § 1008, 42 U.S.C. § 300a-6.

The regulations governing the Title X program have not been substantially updated since 2000. Since then, the need to clarify and ensure compliance with the statutory intent of the program has only increased. The major provisions of the 2019 Title X regulation are summarized below.

Ensures program integrity, consistent with statutory purpose.

- Prohibits the use of Title X funds to perform, promote, refer for, or support abortion as a method of family planning.
- Permits, but no longer requires, nondirective pregnancy counseling, including nondirective counseling on abortion.
- Provides for clear financial and physical separation between Title X and non-Title X activities, reducing any confusion on the part of Title X clinics and the public about permissible Title X activities between the two.
- Improves transparency by requiring grantees to describe subrecipients and referral partnerships, demonstrating a seamless continuum of care.
- Increases accountability, ensuring that grant recipients and their subrecipients understand permissible and impermissible activities under the Title X program.
- Overall, ensures the program is consistent with the underlying statute.

Summary: Of particular significance, the 2019 regulation focuses on compliance with the underlying Title X statute. In addition, it provides clarity between permissible Title X activities and impermissible ones by requiring clear financial and physical separation for Title X funded programs from programs and facilities where abortion is a method of family planning.

Protects the patient/healthcare provider relationship.

- Removes the requirement for abortion referral, replacing it with a prohibition on referral for abortion as a method of family planning.
- Permits, but no longer requires, nondirective pregnancy counseling, including on abortion. It is <u>not</u> a “gag rule”. Health professionals are free to provide non-directive pregnancy counseling, including counseling on abortion.

- Requires referrals for those conditions deemed medically necessary.
- Ensures conscience protections for Title X health providers by eliminating the requirement for providers to counsel on and refer for abortion.

Summary: The 2019 regulation places a high priority on preserving the patient/healthcare provider relationship, in order to promote optimal health for every Title X patient. As such, it requires medically necessary referrals, such as referrals for prenatal care. To preserve open communication between the patient and the healthcare provider, the regulation permits, but no longer requires, nondirective pregnancy counseling, including nondirective counseling on abortion. Consistent with the statutory requirement that no funds may be expended where abortion is a method of family planning, this regulation no longer requires, and affirmatively prohibits, referral for abortion as a method of family planning.

Protects women and children from victimization

- Ensures compliance with state reporting laws and consistency of care for women who visit Title X clinics and are victims of sexual abuse, intimate partner violence, incest, or human trafficking.
- Ensures that children who visit Title X clinics and are victims of rape, incest, child abuse, child molestation, or human trafficking are protected under the law.
- Requires that minors be counseled on how to resist coercion to engage in sexual activity.

Summary: This final rule includes a stronger focus on protecting women and children from being victimized by child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and trafficking. The regulation requires all Title X clinics to provide annual training for staff and to have a site-specific protocol in place to report crime and protect victims.

Boosts meaningful family communication, especially in adolescent family planning

- Meaningfully encourages parent/child communication in family planning decisions, and requires documentation of such encouragement.

Summary: Almost 1 in 5 Title X clients are adolescents. This final rule requires clinics to meaningfully encourage parent/child communication. As required by law, Title X clinics must encourage family participation in family planning decision-making, particularly a minor's decision to seek family planning services. As part of counseling of minors, they should provide practical ways to begin – and maintain – such communication.

Expands coverage, partnerships and innovation

- Focuses on innovative approaches to expand Title X services to unserved and underserved areas.
- Targets sparsely populated areas historically without Title X services.
- Improves Title X services by encouraging diverse and non-traditional Title X partners.
- Prioritizes innovation, partnerships and expansion of the number served by changes in selection criteria for grant proposals.
- Permits those unable to obtain employer-sponsored insurance coverage for certain contraceptive services due to their employer's religious beliefs or moral conviction to be considered for Title X services.

Summary: The final rule adds provisions that are designed to increase the number of patients served within the Title X program by placing special focus on reaching more unserved or underserved areas, by increasing innovation within the program, expanding diversity of grantees and partners, and clarifying the flexibility that program directors have to provide services to those in need of family planning services.

Returns Title X flexibility to states and other grantees

- Restores States' ability to prioritize funding according to the needs of the populations.
- Formally revokes the 2016 rule, which put unnecessary restrictions on states and other grantees and which had been rendered void by a joint resolution of disapproval passed by Congress under the Congressional Review Act and signed by the President.

Summary: The final rule officially revokes a 2016 Title X regulation that limited the ability of States and other Title X grantees to exercise flexibility in choosing their subrecipients. This frees grantees to select clinical providers that meet the Title X needs of their patients, consistent with local needs and sensibilities, and within the statutory and regulatory guidelines.