

May 28, 2019

Ms. Micheala Mitchell
State of Connecticut
Office of Health Strategy
450 Capitol Avenue
Hartford, Connecticut 06106

Re: **Certificate of Need Application: Docket Number 18-32231-CON**
Yale New Haven Hospital
Termination of Primary Care Services
Sixth Order for Late File

Dear Ms. Mitchell:

We are in receipt of the Sixth Order from the Office of Health Strategy (“OHS”) on the Certificate of Need Application by Yale New Haven Hospital dated April 15, 2019 for the property at 150 Sargent Drive in New Haven, and also in receipt of the letter dated May 20, 2019 granting an extension to respond no later the 4:30 pm on May 28, 2019. We have repeated the questions posed by OHS on the subsequent pages, with our response to each question following.

We would also like to provide an update to our response to OHS’s Order Reopening Record dated March 18, 2019. Our response was filed on March 21, 2019 and included, as requested by OHS, a detailed discussion about how the recent revisions to 42 C.F.R. part 59 (the Title X Regulations) might affect the Cornell Scott Hill Health Center and the Fair Haven Community Health Center. In our response, we noted: “The specific anticipated impact of the amended Title X regulations is as of yet unknown. The provisions have not yet been tested or interpreted and are the subject of various lawsuits and litigation.” (Response to Order Reopening Record dated March 18, 2019, page 4 of 33). Since the date of our response, the Title X Regulations have been enjoined from going into effect by three federal judges. Two of the injunctions issued are national in scope (issued by judges in Washington and Oregon) and one is limited to certain plaintiffs in California (issued by a judge in California). Copies of the injunction orders are attached as Exhibit 4. As a result of the national injunctions, the Title X Regulations are enjoined from going into effect until further court action; the federal government is seeking a stay pending appeal.

Please do not hesitate to contact me at 203-688-5721 or jeryl.topalian@ynhh.org if you have any questions or need additional information.

Regards,



Jeryl Topalian
Director Strategy & Regulatory Planning
Office of Strategy Management
Yale New Haven Health

cc: Cynthia Sparer, Sr. VP Operations, YNHHS
Jennifer Willcox, VP Legal Services YNHHS

SIXTH ORDER REGARDING TRANSPORTATION PLAN AND FLOODPLAIN

On April 8, 2019, the Office of Health Strategy (“OHS”) issued an Order to reopen the public hearing to receive additional evidence from the Applicant in the aforementioned Certificate of Need (“CON”) application. OHS has additional questions regarding the Applicant’s submissions.

The Applicant is hereby ordered to provide the following information and/or documents to OHS, via the CON electronic portal, at or before **4:30 p.m. on May 20, 2019**:

1. Documentation detailing the severity and impact of the flooding referenced on page 33 of the Applicant’s response to the Fifth Order (Exhibit FF). Specifically, OHS seeks details with regard to the following:

“Superstorm Sandy impacted the New Haven area on October 29-30, 2012. The storm brought storm surge and coastal flooding that inundated major portions of the coastal New Haven area, including the 150 Sargent Drive site... The surge inundated Long Wharf from the Harbor, passed through the Canal Dock Road underpass beneath Interstate 95, and converged with floodwater in low-lying areas extending to the New Haven Rail Yard.”

This documentation should provide clarity to the extent of damage to or impact of the lot, as well as the building, and include, but not be limited to, any services the Applicant contracted, directly provided or applied for reimbursement for from any source, necessary to repair said damage.

Response:

As was noted in the Response to the Fifth Order, the 150 Sargent Drive location has not flooded during the past ten years. Yale New Haven Hospital (“YNHH”) imaging and other clinical services were active in the building during both Superstorm Sandy and Tropical Storm Irene, and neither the building nor the lot experienced any damage from flooding, nor was access impacted by parking lot ponding, during either storm. As was noted in the page 3 of the Response, there was some water infiltration during one storm due to a poor roof seam. The building was not owned by YNHH at that time, and repairs to roof were made by landlord. The YNHH property manager, who was managing the property at the time of both storms, indicated YNHH did not experience any access issues with the parking lot as a result of either storm, and no repairs were required. The Applicant did not, therefore, contract, directly provide, or apply for reimbursement from any source to repair damages due to either storm, as there were none to the building or parking lot.

YNHH engaged Tighe & Bond, a leader in engineering and environmental consulting services, to assist with the planning and design of proposed renovations to 150 Sargent Drive. The report produced by Tighe & Bond in October, 2018, and provided as Exhibit 2 in the Applicant’s response to the Fifth Order, referenced publicly available information from the City of New Haven and the National Oceanic and Atmospheric Administration (NOAA) regarding the impact of Tropical Storm Irene and Superstorm Sandy on the New Haven Harbor area. The report noted that both storms were severe, with storm surges that “inundated” the area, meaning that normally dry areas experienced rising waters from an existing waterway (see National Weather Service flood definitions https://www.weather.gov/mrx/flood_and_flash and NOAA glossary <https://w1.weather.gov/glossary/index.php?letter=i>). The fact that an area was inundated during a storm does not mean in all cases that flooding was of a depth that would cause damage or limit access to a site. A letter from Tighe & Bond further explaining this is attached as **Exhibit 1**.

2. Official documentation from the City of New Haven evidencing that the Flood Plain Development Permit and Coastal Site Plan Application referenced on page 4 of the Applicant’s response to the Fifth Order (Exhibit FF) have been approved.

Response:

Attached as **Exhibit 2** is a copy of the Flood Plain Development Permit issued on May 16, 2019. Because the project does not involve an addition to the building or a new structure at 150 Sargent Drive, the City does not sign page 2 of the permit.

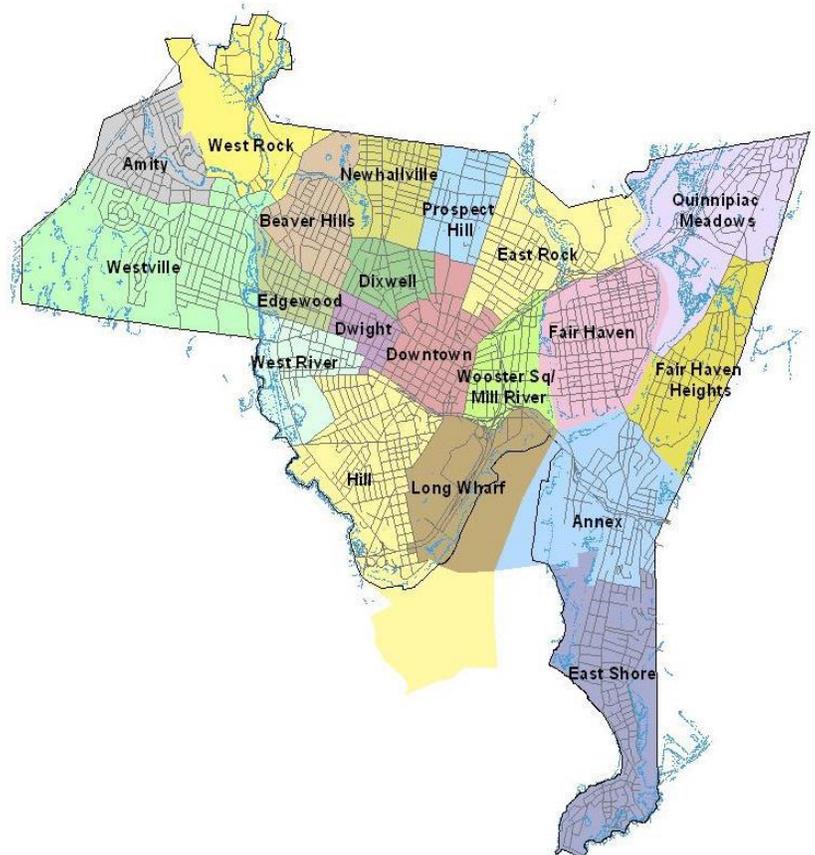
The Board of Alders approved YNH’s Coastal Site Plan Application at their meeting held on May 20, 2019. The Application is expected to be reviewed by the City Plan Commission on May 29, 2019.

3. A unique patient count, by neighborhood, of Yale Primary Care patients for the most recently completed fiscal year.

Response:

Over 14,000 (or almost 60%) of the approximately 25,000 unique patients served by the YNH Primary Care Centers (“PCCs”) reside in neighborhoods in New Haven. The table below shows the unique patient count by neighborhood, and a map of New Haven neighborhoods is provided for reference.

1 Year of data FY 2018	
Neighborhood	Count of Unique Patients
Hill	2,949
Fair Haven	2,004
Newhallville	1,197
West River	881
Edgewood	844
Fair Haven Heights	761
West Rock	758
Annex	706
Dixwell	673
Amity	661
Dwight	652
Quinnipiac Meadows	610
Beaver Hills	514
Wooster Square	374
East Rock	315
Prospect Hill	292
Westville	240
Long Wharf	198
East Shore	132
Downtown	52



4. A detailed transportation plan that:

- identifies all public and private transportation providers offering service to 150 Sargent Drive;
- includes at least two (2) contracted transportation providers that will transport patients from their homes to 150 Sargent Drive, as well as transport eligible patients, upon request, from 150 Sargent Drive to 20 York Street and/or 1450 Chapel Street to access pharmacy and other services as the patient may be referred to by their provider;
- identifies the contracted transportation providers, the specific service standards with which the transportation service providers must comply, and a description of how such compliance will be tracked;
- ensures that at least one (1) of the contracted transportation providers is ADA-compliant;
- ensures that at least one (1) of the contracted providers does not require the use of a smart phone in order to access service;
- includes the eligibility criteria for the ride-sharing service program, subject to OHS review and approval; and
- addresses matters such as wait times for rides and timely drop-offs for appointments.

Response:

A detailed transportation plan is attached as **Exhibit 3**. Specific parts of that plan addressing the questions listed above are identified below:

- **Identify All Public and Private Transportation to 150 Sargent Drive**

The 150 Sargent Drive location is approximately 1.5 miles from the current York Street and St. Raphael PCC locations. It is located off I-91 and I-95, providing easy access by automobile. The site will have ample free parking for patients. A majority of patients (over 2/3) utilize private automobiles to access the primary care clinics.

Additional Public and private transportation providers that offer services to 150 Sargent Drive include:

- CT Transit
- Greater New Haven Transit District (GNHTD)
- Milford Transit District (MTD)
- Veyo
- Coordinated Transportation Solutions (CTS)
- Uber
- Lyft
- Taxi services
- Section 5310 grantees in the greater New Haven area
- Other non-profits in and around New Haven that offer medical transportation services for specific populations: cancer patients, ALS patients, HIV and AIDs patients, individuals receiving HUSKY D or Military Support Program services, and patients with MS, among others.

Additional detail regarding transportation providers is found in Exhibit 3, pages 28 - 29.

- **Contracted Transportation Providers:**

YNHH is contracting with three vendors for transportation services: Uber, Milford Transit District (MTD) and Coordinated Transportation Solutions (CTS). These vendors will all pick up eligible patients from their homes and transport them to 150 Sargent Drive. In certain instances when required or recommended services can only be accessed at the Hospital campuses, eligible patients will be transported from 150 Sargent Drive to one of the Hospital campus locations.¹ Patients coming to the hospital from 150 Sargent Drive for required services, other than pharmacy services, may be eligible for rides from the hospital campus back to their homes, on a case-by-case basis, and as determined to be necessary by their physician. All vendors will transport eligible patients from 150 Sargent Drive to their home.

Contracted Service Providers: Service Standards

Each of the identified transportation providers (CTS, MTD and Uber) has entered into a Memorandum of Understanding (MOU) with YNHH for these services. Copies are attached in the Appendix to Exhibit 3, on pages 37-67. Each MOU outlines the scope of transportation services to be provided, eligibility requirements and service standards and/or community guidelines.²

Vendors shall report to YNHH, on a schedule to be mutually determined, such information as YNHH may reasonably request, including detailed trip information, which shall include request time and date, pick-up and drop-off time and date, pick-up and drop-off location, trip route, distance, duration, fare amount, service type and any complaints received.

YNHH shall track reports provided by vendors on a monthly basis, and if a vendor does not meet the service standards specified, shall be offered 30 day period to remedy the issues. If the issues are not resolved within such 30 day period, YNHH may terminate the relationship.

- **Contracted Service Providers: ADA Compliance**

Both MTD and CTS provide ADA-compliant access for those patients who require this level of transportation assistance.

- **Contracted Service Providers: Smartphone Use**

None of the three vendors listed above require use of a smartphone to schedule transportation services. Rides for eligible patients requiring transportation assistance will be initiated by Health Center staff and scheduled centrally. Details on Contracted Service Providers are found in Exhibit 3, pages 29 and 31.

- **Eligibility Criteria Transportation Services**

Details of the eligibility criteria are found in Exhibit 3, page 30.

¹ YNHH will continue to provide certain prescription medications to 150 Sargent Drive via courier.

² Uber Community Guidelines are found here: <https://www.uber.com/legal/community-guidelines/us-en/>

- **Ride Wait Times and Timely Drop-off**

These matters are addressed in the MOU for each vendor, included as Exhibit 3 Appendix pages 37-67, and in the service standards described on pages 31 and 32 of Exhibit 3. YNHH will monitor and track adherence to service standards as described on page 32 of Exhibit 3.

Additional Information

Recent injunctions pertaining to revisions to 42 C.F.R. part 59 (the Title X Regulations) are attached as **Exhibit 4**.

Exhibits

Exhibit 1	Tighe & Bond Letter
Exhibit 2	Floodplain Development Permit
Exhibit 3	Transportation Plan
Exhibit 4	Title X Additional Information

Exhibit 1



340079034C

May 17, 2019

Ms. Micheala L. Mitchell
Hearing Officer
Office of Health Strategy
State of Connecticut Department of Public Health
450 Capitol Avenue
MS#51OHS
P.O. Box 340308 Hartford, CT 06134
micheala.mitchell@ct.gov

**Re: Certificate of Need Application by Yale New Haven Hospital
Termination of Outpatient Primary Care Centers (18-32231-CON)**

Dear Attorney Mitchell:

Tighe & Bond, Inc. (Tighe & Bond) is a leader in engineering and environmental consulting services with offices in Connecticut, Massachusetts, New Hampshire, New York and Rhode Island. *Engineering News Record* annually ranks Tighe & Bond among the top design and environmental engineering firms nationally. We provide a full array of services, including site planning and design, environmental consulting, and coastal and waterfront solutions.

We were engaged by Yale New Haven Hospital (YNHH) to assist with the planning and design of proposed renovations to 150 Sargent Drive. As part of that engagement, we reviewed compliance of the existing building with current City Flood Damage Prevention Ordinance Regulations and issued a report on our findings (we understand that a copy of the report has been provided to your office). In preparing the report, we referenced publicly available information from the City of New Haven and the National Oceanic and Atmospheric Administration (NOAA) regarding the impact of Tropical Storm Irene and Superstorm Sandy on the New Haven Harbor area. Both storms were severe with storm surges that inundated the area, meaning that normally dry areas experienced rising waters from an existing waterway (see National Weather Service flood definitions - https://www.weather.gov/mrx/flood_and_flash and NOAA glossary- <https://w1.weather.gov/glossary/index.php?letter=i>). The fact that an area was inundated during a storm does not mean in all cases that flooding was of a depth that would cause damage or limit access to a site. See, for example, the science behind flood mapping developed by the U.S. Department of the Interior's United States Geological Survey here: https://www.usgs.gov/mission-areas/water-resources/science/flood-inundation-mappingscience?qt-science_center_objects=0#qt-science_center_objects.

Once it was identified that 150 Sargent Drive was subject to floodplain requirements, Tighe & Bond began working with YNHH, the City of New Haven and the Connecticut Department of Energy and Environmental Protection to determine the required permits and necessary precautions to flood proof the building.





Tighe & Bond personnel do not have first-hand knowledge of the impact of either Tropical Storm Irene or Superstorm Sandy on the building at 150 Sargent Drive, but available records indicate that the peak storm surge elevations were below the first-floor elevation of 150 Sargent Drive. These observations are consistent with the extent and depth of flooding that would be expected based on the NOAA storm surge elevation.

We have been informed that a YNHH Maintenance Specialist weathered Sandy and Irene onsite at 150 Sargent Drive. He indicated that the parking area of 150 Sargent Drive did **NOT** flood. In the area of 150 Sargent Drive the flood waters never advanced north of the I95 median. The surrounding streets in the immediate area also did not flood. That said, Sargent Drive in the area of Ikea did flood and the underpass south of Ikea was largely impassable. Despite the issues by Ikea, the 150 Sargent Drive site remained accessible from Sargent Drive and also accessible from the North via the Church Street extension.

I hope that this serves to clarify the report and our review of the 150 Sargent Drive Site. Please feel free contact me if you have any questions or if we can provide additional information.

Very truly yours,

TIGHE & BOND, INC.

A handwritten signature in black ink, appearing to read "Joseph Canas".

Joseph Canas, PE, LEED AP, CFM
Principal Engineer

A handwritten signature in black ink, appearing to read "John W. Block".

John W. Block, PE, LS
Senior Vice President



Exhibit 2

FLOOD PLAIN DEVELOPMENT PERMIT

CITY OF NEW HAVEN, CONNECTICUT

Instructions: Print or type information in space provided, check box where appropriate.

Address of Application Parcel(s):

150 Sargent Drive

a/k/a:

Total Parcel Size in Square Feet: 168,142

Tax Map-Block-Parcel(s): 228/1304/00600

Flood Map Community-Panel Number: ~~090004~~
09009C0441J

For City Use Only

File # _____
Building Permit # _____
Date _____
Fee Paid: _____
Census Tract-Block: _____

APPLICATION FOR FLOOD PLAIN DEVELOPMENT PERMIT

Yes No

1. Have all permits from Federal, State or Local Government Agencies requiring prior approval been received?
2. Will any watercourse be altered or relocated as a result of the proposed development? IF YES, attach description.
3. Are plans included for any walls to be used to enclose space below base flood elevation?
4. Are plans included, in duplicate and drawn to scale, showing the nature, location, dimensions and elevations of area in question, existing and/or proposed structures, fill, storage of materials, drainage facilities, and location of foregoings?
5. Does this Parcel have Flood Insurance?
IF YES, Flood Insurance Policy #: US00027516PR19A Expiration Date: May 9, 2020

6. **Type of Development:** Value of Existing Structure: \$ 7.1M
Cost of Alteration/Addition/Improvement: \$ 18.4M

Excavation Fill Grading Paving Buildings or Other Structure Substantial Improvements
Other alterations inside Regulatory Floodway Limits. Specify: _____

7. Owner Information & Consent (If Other than Developer/Agent)

Name Heather Eastman Daytime Phone: (203)688-4368
Firm Yale New Haven Hospital Home Business Answering Service
Street Address 789 Howard Ave Fax: _____
City New Haven State CT Zip 06519

The undersigned, as owner of the property, hereby consents to necessary and proper inspections of the above mentioned property by agents of the City at reasonable times before and after an application is made.
Dated: May 16, 2020 Heather Eastman
Signature of Owner

8. Developer (If other than Owner)

Name _____ Daytime Phone: _____
Firm _____ Home Business Answering Service
Street Address _____ Fax: _____
City _____ State _____ Zip _____
I am the (Check One): Property Owner Option Holder Other (Describe _____)

9. Authorized Applicant/Agent Information & Certification

Name Same as Owner Daytime Phone: _____
Firm _____ Home Business Answering Service
Street Address _____ Fax: _____
City _____ State _____ Zip _____

As Applicant/Agent for the Property Owner Developer, the undersigned is familiar with all of the information provided in this application and is aware that any permit obtained through deception, inaccurate or misleading information is subject to revocation and penalties.
Dated: May 16, 2020 Heather Eastman
Signature of Applicant Agent

The section in this box shall be filled in with the application for a Building Permit.

CERTIFICATION OF ELEVATION FOR BUILDING PERMIT APPLICATION
 NGVD = National Geodetic Vertical Datum of 1929.

I hereby certify that this application meets the criteria of §5.3.1. of the New Haven Flood Damage Prevention Ordinance:

- The lowest floor including basement of the above referenced structure will be constructed at 12.9 Feet NGVD exist.
- Elevation to which any structure will be floodproofed, in relation to mean sea level is 13.04 Feet NGVD.
- The net effect of development will cause no more than one (1) foot rise in the water surface of the base flood elevation.
- The development will have no adverse effect on the floodplain.

Signature J. Sak CONNECTICUT PE LS 11302
 JAMES N. SAKONCHICK State 1-29-2019 Registration No. _____, 20__

Print Name of Land Surveyor Engineer Architect Date _____

This Certification may only be signed by a Connecticut Licensed land surveyor, engineer or architect.
 An A-2 Survey is required if the total project value is more than \$25,000.

For City Use Only, Reviewed and Approved by:
 If box is checked an addition or new structure is proposed and signoff by City Plan and City Engineer is required.

Building Dept. 30 City Plan _____ City Engineer _____
 Dated: 5/17/2017 Dated: / / 20__ Dated: / / 20__

WWW: 977DP.DOC 12/30/96 6:26 PM

NOTE 12.9 FT NGVD 29 = 11.86 FT NAVD 88
 13.04 FT NGVD 29 = 12.00 FT NAVD 88
 EXISTING ELEVATOR PIT INSIDE BUILDING HAS A FLOOR 4 FT BELOW
 THAN LISTED LOWEST FLOOR. THIS IS UNINHABITED SPACE.

This section shall be filled out following completion of the permitted project.

CERTIFICATION OF AS BUILT ELEVATION

I hereby certify that this project as built meets the criteria of §5.3.1. of the New Haven Flood Damage Prevention Ordinance:

- The lowest floor including basement of the above referenced structure has been constructed at _____ Feet NGVD.
- Elevation to which any structure has been floodproofed, in relation to mean sea level is _____ Feet NGVD.
- The net effect of development will cause no more than one (1) foot rise in the water surface of the base flood elevation.
- The development will have no adverse effect on the floodplain.

Signature _____ State _____ Registration No. _____, 20__

Print Name of Land Surveyor Engineer Architect Date _____

This Certificate may only be signed by a Connecticut Licensed land surveyor, engineer or architect.



FEMA

NATIONAL FLOOD INSURANCE PROGRAM

ELEVATION CERTIFICATE

AND

INSTRUCTIONS

2015 EDITION

OMB No. 1660-0008
Expiration Date: November 30, 2018

U.S. DEPARTMENT OF HOMELAND SECURITY
Federal Emergency Management Agency
National Flood Insurance Program

ELEVATION CERTIFICATE AND INSTRUCTIONS

Paperwork Reduction Act Notice

Public reporting burden for this data collection is estimated to average 3.75 hours per response. The burden estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and submitting this form. You are not required to respond to this collection of information unless a valid OMB control number is displayed on this form. Send comments regarding the accuracy of the burden estimate and any suggestions for reducing the burden to: Information Collections Management, Department of Homeland Security, Federal Emergency Management Agency, 1800 South Bell Street, Arlington, VA 20598-3005, Paperwork Reduction Project (1660-0008). **NOTE: Do not send your completed form to this address.**

Privacy Act Statement

Authority: Title 44 CFR § 61.7 and 61.8.

Principal Purpose(s): This information is being collected for the primary purpose of estimating the risk premium rates necessary to provide flood insurance for new or substantially improved structures in designated Special Flood Hazard Areas.

Routine Use(s): The information on this form may be disclosed as generally permitted under 5 U.S.C. § 552a(b) of the Privacy Act of 1974, as amended. This includes using this information as necessary and authorized by the routine uses published in DHS/FEMA-003 – National Flood Insurance Program Files System or Records Notice 73 Fed. Reg. 77747 (December 19, 2008); DHS/FEMA/NFIP/LOMA-1 – National Flood Insurance Program (NFIP) Letter of Map Amendment (LOMA) System of Records Notice 71 Fed. Reg. 7990 (February 15, 2006); and upon written request, written consent, by agreement, or as required by law.

Disclosure: The disclosure of information on this form is voluntary; however, failure to provide the information requested may result in the inability to obtain flood insurance through the National Flood Insurance Program or the applicant may be subject to higher premium rates for flood insurance. Information will only be released as permitted by law.

Purpose of the Elevation Certificate

The Elevation Certificate is an important administrative tool of the National Flood Insurance Program (NFIP). It is to be used to provide elevation information necessary to ensure compliance with community floodplain management ordinances, to determine the proper insurance premium rate, and to support a request for a Letter of Map Amendment (LOMA) or Letter of Map Revision based on fill (LOMR-F).

The Elevation Certificate is required in order to properly rate Post-FIRM buildings, which are buildings constructed after publication of the Flood Insurance Rate Map (FIRM), located in flood insurance Zones A1–A30, AE, AH, A (with BFE), VE, V1–V30, V (with BFE), AR, AR/A, AR/AE, AR/A1–A30, AR/AH, and AR/AO. The Elevation Certificate is not required for Pre-FIRM buildings unless the building is being rated under the optional Post-FIRM flood insurance rules.

As part of the agreement for making flood insurance available in a community, the NFIP requires the community to adopt floodplain management regulations that specify minimum requirements for reducing flood losses. One such requirement is for the community to obtain the elevation of the lowest floor (including basement) of all new and substantially improved buildings, and maintain a record of such information. The Elevation Certificate provides a way for a community to document compliance with the community's floodplain management ordinance.

Use of this certificate does not provide a waiver of the flood insurance purchase requirement. Only a LOMA or LOMR-F from the Federal Emergency Management Agency (FEMA) can amend the FIRM and remove the Federal mandate for a lending institution to require the purchase of flood insurance. However, the lending institution has the option of requiring flood insurance even if a LOMA/LOMR-F has been issued by FEMA. The Elevation Certificate may be used to support a LOMA or LOMR-F request. Lowest floor and lowest adjacent grade elevations certified by a surveyor or engineer will be required if the certificate is used to support a LOMA or LOMR-F request. A LOMA or LOMR-F request must be submitted with either a completed FEMA MT-EZ or MT-1 package, whichever is appropriate.

This certificate is used only to certify building elevations. A separate certificate is required for floodproofing. Under the NFIP, non-residential buildings can be floodproofed up to or above the Base Flood Elevation (BFE). A floodproofed building is a building that has been designed and constructed to be watertight (substantially impermeable to floodwaters) below the BFE. Floodproofing of residential buildings is not permitted under the NFIP unless FEMA has granted the community an exception for residential floodproofed basements. The community must adopt standards for design and construction of floodproofed basements before FEMA will grant a basement exception. For both floodproofed non-residential buildings and residential floodproofed basements in communities that have been granted an exception by FEMA, a floodproofing certificate is required.

Additional guidance can be found in FEMA Publication 467-1, Floodplain Management Bulletin: Elevation Certificate, available on FEMA's website at <https://www.fema.gov/media-library/assets/documents/3539?id=1727>.

U.S. DEPARTMENT OF HOMELAND SECURITY
 Federal Emergency Management Agency
 National Flood Insurance Program

OMB No. 1660-0008
 Expiration Date: November 30, 2018

ELEVATION CERTIFICATE

Important: Follow the instructions on pages 1-9.

Copy all pages of this Elevation Certificate and all attachments for (1) community official, (2) insurance agent/company, and (3) building owner.

SECTION A – PROPERTY INFORMATION				FOR INSURANCE COMPANY USE	
A1. Building Owner's Name YALE-NEW HAVEN HOSPITAL, INC.				Policy Number:	
A2. Building Street Address (including Apt., Unit, Suite, and/or Bldg. No.) or P.O. Route and Box No. 150 SARGENT DRIVE				Company NAIC Number:	
City NEW HAVEN		State Connecticut		ZIP Code 06519	
A3. Property Description (Lot and Block Numbers, Tax Parcel Number, Legal Description, etc.) MBLU: 228/1304/00600; ACCT#: 228 1304 00600; VOLUME: 9679; PAGE: 254; PID: 13212					
A4. Building Use (e.g., Residential, Non-Residential, Addition, Accessory, etc.) <u>NON-RESIDENTIAL/COMMERCIAL</u>					
A5. Latitude/Longitude: Lat. <u>41°17'33.71"N</u> Long. <u>72°55'19.20" W</u> Horizontal Datum: <input type="checkbox"/> NAD 1927 <input checked="" type="checkbox"/> NAD 1983					
A6. Attach at least 2 photographs of the building if the Certificate is being used to obtain flood insurance.					
A7. Building Diagram Number <u>1A</u>					
A8. For a building with a crawlspace or enclosure(s):					
a) Square footage of crawlspace or enclosure(s) <u>N/A</u> sq ft					
b) Number of permanent flood openings in the crawlspace or enclosure(s) within 1.0 foot above adjacent grade <u>N/A</u>					
c) Total net area of flood openings in A8.b <u>N/A</u> sq in					
d) Engineered flood openings? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No					
A9. For a building with an attached garage:					
a) Square footage of attached garage <u>N/A</u> sq ft					
b) Number of permanent flood openings in the attached garage within 1.0 foot above adjacent grade <u>N/A</u>					
c) Total net area of flood openings in A9.b <u>N/A</u> sq in					
d) Engineered flood openings? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No					
SECTION B – FLOOD INSURANCE RATE MAP (FIRM) INFORMATION					
B1. NFIP Community Name & Community Number NEW HAVEN, CITY OF; 090084			B2. County Name NEW HAVEN		B3. State Connecticut
B4. Map/Panel Number 441	B5. Suffix J	B6. FIRM Index Date 06-08-2013	B7. FIRM Panel Effective/ Revised Date 06-08-2013	B8. Flood Zone(s) AE	B9. Base Flood Elevation(s) (Zone AO, use Base Flood Depth) 11'(building) & 12'(rear parking lot)
B10. Indicate the source of the Base Flood Elevation (BFE) data or base flood depth entered in Item B9: <input type="checkbox"/> FIS Profile <input checked="" type="checkbox"/> FIRM <input type="checkbox"/> Community Determined <input type="checkbox"/> Other/Source: _____					
B11. Indicate elevation datum used for BFE in Item B9: <input type="checkbox"/> NGVD 1929 <input checked="" type="checkbox"/> NAVD 1988 <input type="checkbox"/> Other/Source: _____					
B12. Is the building located in a Coastal Barrier Resources System (CBRS) area or Otherwise Protected Area (OPA)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Designation Date: _____ <input type="checkbox"/> CBRS <input type="checkbox"/> OPA					

ELEVATION CERTIFICATE

OMB No. 1860-0008
 Expiration Date: November 30, 2018

IMPORTANT: In these spaces, copy the corresponding information from Section A.			FOR INSURANCE COMPANY USE
Building Street Address (including Apt., Unit, Suite, and/or Bldg. No.) or P.O. Route and Box No. 150 SARGENT DRIVE			Policy Number:
City NEW HAVEN	State Connecticut	ZIP Code 06519	Company NAIC Number

SECTION C – BUILDING ELEVATION INFORMATION (SURVEY REQUIRED)

C1. Building elevations are based on: Construction Drawings* Building Under Construction* Finished Construction
 *A new Elevation Certificate will be required when construction of the building is complete.

C2. Elevations – Zones A1–A30, AE, AH, A (with BFE), VE, V1–V30, V (with BFE), AR, AR/A, AR/AE, AR/A1–A30, AR/AH, AR/AO.
 Complete Items C2.a–h below according to the building diagram specified in Item A7. In Puerto Rico only, enter meters.
 Benchmark Utilized: CITY BM NGVD29 CONVERT-88 Vertical Datum: NAVD 88

Indicate elevation datum used for the elevations in items a) through h) below.
 NGVD 1929 NAVD 1988 Other/Source: _____

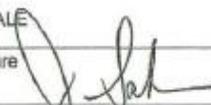
Datum used for building elevations must be the same as that used for the BFE.

		Check the measurement used.
a) Top of bottom floor (including basement, crawlspace, or enclosure floor)	7.86	<input checked="" type="checkbox"/> feet <input type="checkbox"/> meters
b) Top of the next higher floor	11.86	<input checked="" type="checkbox"/> feet <input type="checkbox"/> meters
c) Bottom of the lowest horizontal structural member (V Zones only)	N/A	<input type="checkbox"/> feet <input type="checkbox"/> meters
d) Attached garage (top of slab)	N/A	<input type="checkbox"/> feet <input type="checkbox"/> meters
e) Lowest elevation of machinery or equipment servicing the building (Describe type of equipment and location in Comments)	7.86	<input checked="" type="checkbox"/> feet <input type="checkbox"/> meters
f) Lowest adjacent (finished) grade next to building (LAG)	7.80	<input checked="" type="checkbox"/> feet <input type="checkbox"/> meters
g) Highest adjacent (finished) grade next to building (HAG)	11.35	<input checked="" type="checkbox"/> feet <input type="checkbox"/> meters
h) Lowest adjacent grade at lowest elevation of deck or stairs, including structural support	8.80	<input checked="" type="checkbox"/> feet <input type="checkbox"/> meters

SECTION D – SURVEYOR, ENGINEER, OR ARCHITECT CERTIFICATION

This certification is to be signed and sealed by a land surveyor, engineer, or architect authorized by law to certify elevation information. I certify that the information on this Certificate represents my best efforts to interpret the data available. I understand that any false statement may be punishable by fine or imprisonment under 18 U.S. Code, Section 1001.

Were latitude and longitude in Section A provided by a licensed land surveyor? Yes No Check here if attachments.

Certifier's Name JAMES SAKONCHICK	License Number CT 11302
Title PRESIDENT	
Company Name KRATZERT JONES & ASSOCIATES, INC	
Address 1755 MERIDEN-WATERBURY ROAD LAFAYETTE SQUARE UNIT 3, PO BOX 337	
City MILLDALE	State Connecticut
Signature 	Date 10-10-2018
	Telephone (860) 621-3638
	Ext.



Copy all pages of this Elevation Certificate and all attachments for (1) community official, (2) insurance agent/company, and (3) building owner.

Comments (including type of equipment and location, per C2(e), if applicable)
 Source of Latitude & Longitude: Google Earth;
 Source of elevations were city redevelopment maps using NGVD 29 with conversion to NAVD 88 using website listed on FIRM map.
 Elevations rough checked using Equipment used to Establish Elevation: GPS (Pro Mark-500) dual frequency receiver, Carlson Software; Real Time Kinematic (RTK) averaging with a Network Subscription (Superior) with plus or minus 0.15 ft accuracy.
 THE PRIMARY BUILDING HAS A MAIN FLOOR ELEVATION OF 11.86. TWO STAIRWAYS EXIT AT ELEV. 8.8 WITH HEATER AT ELEV. 9.5. THERE ARE TWO ELEVATOR PITS AT ELEVATION 7.86 WITH INCIDENTAL EQUIPMENT. THE PRIMARY ELEVATOR EQUIPMENT AND MOTORS ARE ABOVE ELEVATION 11.86. ALL ELEVATIONS AT NAVD 88.

ELEVATION CERTIFICATE

OMB No. 1660-0008
 Expiration Date: November 30, 2018

IMPORTANT: In these spaces, copy the corresponding information from Section A.			FOR INSURANCE COMPANY USE
Building Street Address (including Apt., Unit, Suite, and/or Bldg. No.) or P.O. Route and Box No. 150 SARGENT DRIVE			Policy Number:
City NEW HAVEN	State Connecticut	ZIP Code 06519	Company NAIC Number
SECTION E – BUILDING ELEVATION INFORMATION (SURVEY NOT REQUIRED) FOR ZONE AO AND ZONE A (WITHOUT BFE)			
<p>For Zones AO and A (without BFE), complete Items E1–E5. If the Certificate is intended to support a LOMA or LOMR-F request, complete Sections A, B, and C. For Items E1–E4, use natural grade, if available. Check the measurement used. In Puerto Rico only, enter meters.</p> <p>E1. Provide elevation information for the following and check the appropriate boxes to show whether the elevation is above or below the highest adjacent grade (HAG) and the lowest adjacent grade (LAG).</p> <p style="margin-left: 20px;">a) Top of bottom floor (including basement, crawlspace, or enclosure) is _____ <input type="checkbox"/> feet <input type="checkbox"/> meters <input type="checkbox"/> above or <input type="checkbox"/> below the HAG.</p> <p style="margin-left: 20px;">b) Top of bottom floor (including basement, crawlspace, or enclosure) is _____ <input type="checkbox"/> feet <input type="checkbox"/> meters <input type="checkbox"/> above or <input type="checkbox"/> below the LAG.</p> <p>E2. For Building Diagrams 6–9 with permanent flood openings provided in Section A Items 8 and/or 9 (see pages 1–2 of Instructions), the next higher floor (elevation C2.b in the diagrams) of the building is _____ <input type="checkbox"/> feet <input type="checkbox"/> meters <input type="checkbox"/> above or <input type="checkbox"/> below the HAG.</p> <p>E3. Attached garage (top of slab) is _____ <input type="checkbox"/> feet <input type="checkbox"/> meters <input type="checkbox"/> above or <input type="checkbox"/> below the HAG.</p> <p>E4. Top of platform of machinery and/or equipment servicing the building is _____ <input type="checkbox"/> feet <input type="checkbox"/> meters <input type="checkbox"/> above or <input type="checkbox"/> below the HAG.</p> <p>E5. Zone AO only: If no flood depth number is available, is the top of the bottom floor elevated in accordance with the community's floodplain management ordinance? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown. The local official must certify this information in Section G.</p>			
SECTION F – PROPERTY OWNER (OR OWNER'S REPRESENTATIVE) CERTIFICATION			
<p>The property owner or owner's authorized representative who completes Sections A, B, and E for Zone A (without a FEMA-issued or community-issued BFE) or Zone AO must sign here. The statements in Sections A, B, and E are correct to the best of my knowledge.</p> <p>Property Owner or Owner's Authorized Representative's Name</p> <p>Address _____ City _____ State _____ ZIP Code _____</p> <p>Signature _____ Date _____ Telephone _____</p> <p>Comments</p> <div style="border: 1px solid black; height: 150px; width: 100%; margin-top: 10px;"></div> <p style="text-align: right; margin-top: 10px;"><input type="checkbox"/> Check here if attachments.</p>			

ELEVATION CERTIFICATE

OMB No. 1660-0008
 Expiration Date: November 30, 2018

IMPORTANT: In these spaces, copy the corresponding information from Section A.		FOR INSURANCE COMPANY USE	
Building Street Address (including Apt., Unit, Suite, and/or Bldg. No.) or P.O. Route and Box No. 150 SARGENT DRIVE		Policy Number:	
City NEW HAVEN	State Connecticut	ZIP Code 06519	Company NAIC Number
SECTION G – COMMUNITY INFORMATION (OPTIONAL)			
<p>The local official who is authorized by law or ordinance to administer the community's floodplain management ordinance can complete Sections A, B, C (or E), and G of this Elevation Certificate. Complete the applicable item(s) and sign below. Check the measurement used in Items G8–G10. In Puerto Rico only, enter meters.</p> <p>G1. <input type="checkbox"/> The information in Section C was taken from other documentation that has been signed and sealed by a licensed surveyor, engineer, or architect who is authorized by law to certify elevation information. (Indicate the source and date of the elevation data in the Comments area below.)</p> <p>G2. <input type="checkbox"/> A community official completed Section E for a building located in Zone A (without a FEMA-issued or community-issued BFE) or Zone AO.</p> <p>G3. <input type="checkbox"/> The following information (Items G4–G10) is provided for community floodplain management purposes.</p>			
G4. Permit Number	G5. Date Permit Issued	G6. Date Certificate of Compliance/Occupancy Issued	
<p>G7. This permit has been issued for: <input type="checkbox"/> New Construction <input type="checkbox"/> Substantial Improvement</p> <p>G8. Elevation of as-built lowest floor (including basement) of the building: _____ <input type="checkbox"/> feet <input type="checkbox"/> meters Datum _____</p> <p>G9. BFE or (in Zone AO) depth of flooding at the building site: _____ <input type="checkbox"/> feet <input type="checkbox"/> meters Datum _____</p> <p>G10. Community's design flood elevation: _____ <input type="checkbox"/> feet <input type="checkbox"/> meters Datum _____</p>			
Local Official's Name		Title	
Community Name		Telephone	
Signature		Date	
<p>Comments (including type of equipment and location, per C2(e), if applicable)</p> <p style="text-align: right;"><input type="checkbox"/> Check here if attachments.</p>			

BUILDING PHOTOGRAPHS

See Instructions for Item A6.

OMB No. 1660-0008

Expiration Date: November 30, 2018

ELEVATION CERTIFICATE

IMPORTANT: In these spaces, copy the corresponding information from Section A.

FOR INSURANCE COMPANY USE

Building Street Address (including Apt., Unit, Suite, and/or Bldg. No.) or P.O. Route and Box No.
 150 SARGENT DRIVE

Policy Number:

City
 NEW HAVEN

State
 Connecticut

ZIP Code
 06519

Company NAIC Number

If using the Elevation Certificate to obtain NFIP flood insurance, affix at least 2 building photographs below according to the instructions for Item A6. Identify all photographs with date taken; "Front View" and "Rear View"; and, if required, "Right Side View" and "Left Side View." When applicable, photographs must show the foundation with representative examples of the flood openings or vents, as indicated in Section A8. If submitting more photographs than will fit on this page, use the Continuation Page.



Photo One

Photo One Caption FRONT VIEW FROM SARGENT DRIVE

Clear Photo One



Photo Two

Photo Two Caption LEFT SIDE VIEW FROM CHURCH STREET EXTENSION SIDE ROAD

Clear Photo Two

BUILDING PHOTOGRAPHS

Continuation Page

OMB No. 1660-0008
 Expiration Date: November 30, 2018

ELEVATION CERTIFICATE

IMPORTANT: In these spaces, copy the corresponding information from Section A.			FOR INSURANCE COMPANY USE
Building Street Address (including Apt., Unit, Suite, and/or Bldg. No.) or P.O. Route and Box No. 150 SARGENT DRIVE			Policy Number:
City NEW HAVEN	State Connecticut	ZIP Code 06519	Company NAIC Number

If submitting more photographs than will fit on the preceding page, affix the additional photographs below. Identify all photographs with: date taken; "Front View" and "Rear View"; and, if required, "Right Side View" and "Left Side View." When applicable, photographs must show the foundation with representative examples of the flood openings or vents, as indicated in Section A8.



Photo Three

Photo Three Caption REAR VIEW FROM PARKING LOT

Clear Photo Three



Photo Four

Photo Four Caption RIGHT SIDE VIEW

Clear Photo Four

Exhibit 3



Transportation Plan

New Haven Primary Care Consortium (NHPCC)

Introduction

Yale New Haven Hospital (YNHH) offers a range of services to meet the needs of medically underserved patients throughout the state. Some of YNHH's many community initiatives to benefit people of greater New Haven and surrounding communities include the AIDS care program, cancer screening program, parenting support programs, school-based health centers, and sickle cell program, as well as primary care through its primary care centers (PCCs). YNHH won the 2017 Foster G. McGaw Prize for Excellence in Community Service, one of the nation's most esteemed honors in health care, awarded annually by the American Hospital Association (AHA), to one hospital that has distinguished itself by efforts to improve the health and well-being of the people in its communities.

Fair Haven Community Health Clinic, Inc. (FHCHC) is a federally qualified health center (FQHC) and is dually certified as a patient-centered medical home (PCMH) by both NCQA and the Joint Commission. FHCHC offers a wide range of services including comprehensive primary care, dental, behavioral health and substance abuse care at seven locations in southern Connecticut, including New Haven and East Haven. FHCHC also staffs 6 school-based health centers throughout the area as well as a portable and mobile dental program within New Haven Schools.

Cornell Scott-Hill Health Corporation (CSHHC) is a federally qualified health center (FQHC), established as the first community health center in Connecticut. CSHHC has grown and expanded since then, opening new sites to create greater access. CSHHC currently has 19 locations throughout New Haven County, including New Haven, West Haven, Ansonia and Derby; providing a range of services to residents in New Haven and surrounding towns, and also supports five school-based health centers in New Haven.

YNHH, CSHHC and Fair Haven Community Health Center FHCHC represent the three largest providers of primary care services in the greater New Haven area. In 2015, the three institutions came together to form the New Haven Primary Care Consortium (NHPCC) to improve the quality of primary care services and the efficiency of how that care is delivered to underserved patient populations in the greater New Haven area.

YNHH will work with the two local FQHCs to transition YNHH's PCCs to new primary care clinics – Adult Medicine, Women's Health and Pediatrics - at a new location at 150 Sargent Drive in New Haven. The new clinics will be operated under the respective licenses and management of CSHHC and FHCHC.

Through NHPCC, each FQHC will leverage its existing clinical strengths and capabilities in the provision of culturally competent medical care, while working collaboratively with YNHH to help create an optimal patient care experience. Patients currently receiving care in the YNHH PCCs will have access to services and care models that are not currently provided by YNHH (e.g., embedded behavioral health), while continuing to receive care from their existing providers. This collaboration, along with the adoption of the EPIC electronic health record, will prevent some of the fragmentation and duplication that typically occurs as patients receive care from multiple entities. By working collaboratively on access and quality issues through the NHPCC, the services offered to current YNHH PCC patients will be enhanced.

Access to Care

YNHH currently provides primary care services to more than 25,000 patients in the greater New Haven region through its PCCs located at the York Street and St. Raphael campuses and in Hamden (the YNHH PCCs). Services are currently provided in multiple locations, some of which are cramped and outdated and located in old facilities. Parking is limited, and the expense of parking was cited by patients as a barrier to access in a survey conducted at Adult Medicine Clinic on Chapel Street in November, 2014.

The Greater New Haven Community Index 2016, which is the most current area Community Health Needs Assessment (CHNA), cites the ability for area residents to access quality, affordable and convenient medical care as a major concern. Barriers to accessing health care included cost, inability to find time to get to a physician's office, lack of transportation access, belief that routine or preventive health care is not necessary, and a lack of health care insurance.³

The NHPCC members agreed that any new location chosen for this initiative needed to meet the following requirements:

- Large enough to accommodate 100,000 or more annual patient visits
- Zoned for medical care
- Easy access to parking and public transportation services for the community

After a detailed search, 150 Sargent Drive in New Haven, CT was identified as the optimal location. This location is less than 1.5 miles from YNHH's York Street and Saint Raphael campuses. It is on a bus line and closer to the highways I-95 and I-91 than the current sites. The site has substantial free parking for patients who wish to drive.

During the process of forming the NHPCC, and once the site to relocate the existing PCCs was identified, a series of community outreach meetings were held across the greater New Haven region to discuss the proposed NHPCC plans. Although transportation issues, especially parking, had been cited as a barrier to accessing care at the current PCC locations, the proposed location identified new concerns, especially for those residents close enough to the current locations to be accessible by walking.

To address these concerns, YNHH evaluated demographics of current PCC patients. Approximately 11,000 unique patients (about 40%) reside in towns outside of New Haven, with residents of West Haven, Hamden and East Haven comprising over half of those patients. Over 14,000 (or almost 60%) of the approximately 25,000 unique patients served by the YNHH PCCs reside in neighborhoods in New Haven.

There are no changes to this population anticipated when services are relocated to 150 Sargent Drive. Additionally, the payer mix at 150 Sargent is projected to be unchanged from the current payer mix of 75% Medicaid, 12% Medicare, 7% Commercial Insurers, and 6% Uninsured.

YNHH conducted a statistically-significant survey of over 2,500 current patients of the PCCs from June 19, 2018 through September 5, 2018. Patients were surveyed about the modes of transportation they use to access care at the PCCs (driving, walking, public transportation, etc.) and the challenges they face in doing so. The survey was administered at all PCC locations at York Street, Saint Raphael Campus, and Hamden. Surveys were administered to patients in the language of their preference (English, Spanish or Arabic) as they arrived at the PCC, and collected at departure.

³ Greater New Haven Community Index 2016, page 37

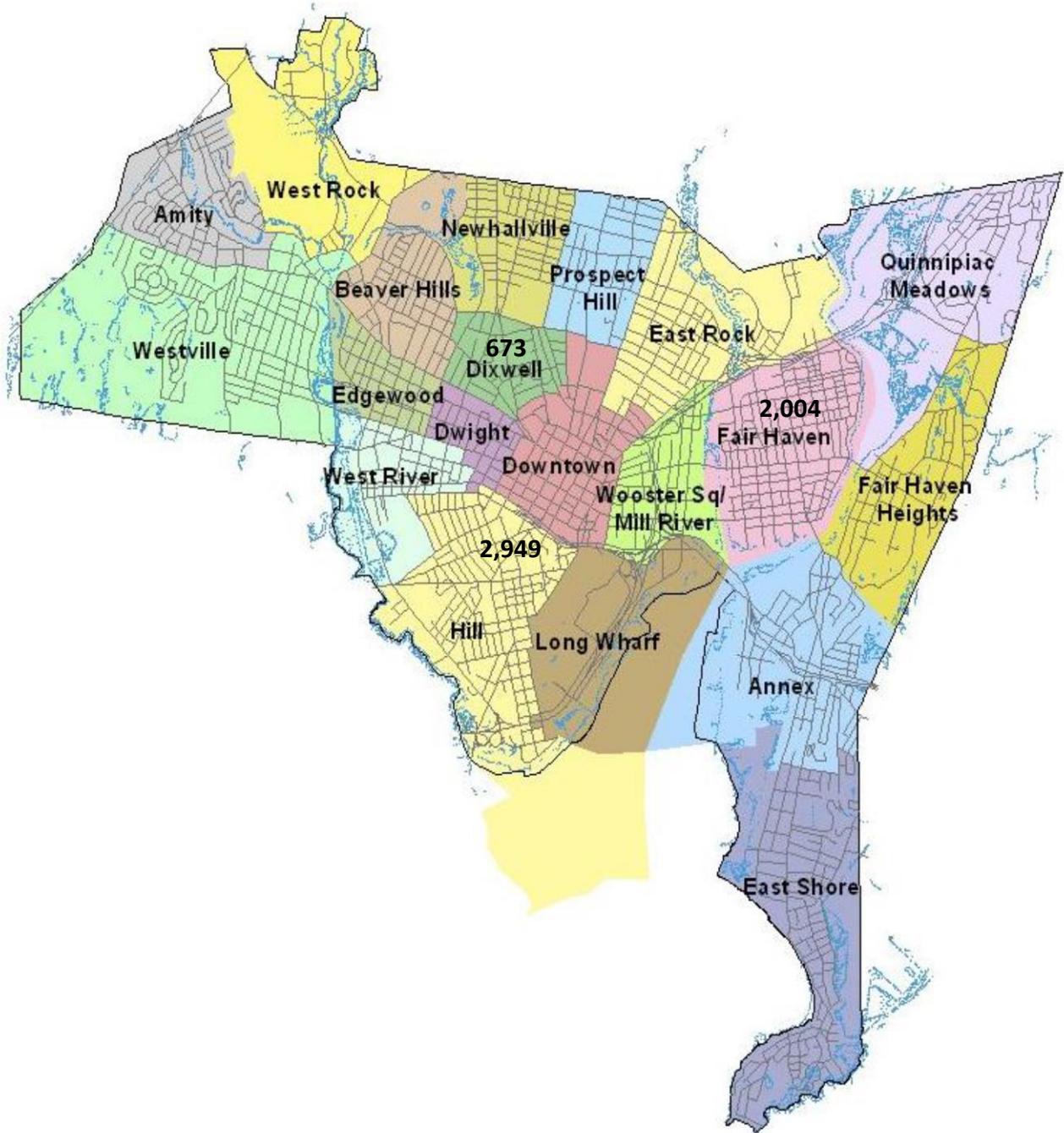
Results of the survey showed that nearly 30% of all respondents noted they had missed an appointment due to transportation barriers. Modes of transportation used to get to appointments included:⁴

- 66% utilize a car
- 15% use public transportation
- 10% walk
- 5% use a medical taxi
- 3% use taxi/Uber/Lyft
- 1% designated “other”

The table below shows the number of unique PCC patients by New Haven neighborhood of residence, and a map designating the New Haven neighborhoods is provided for reference on the following page.

FY 2018 PCC Patients by Neighborhood	
Neighborhood	Number of Unique Patients
Hill	2,949
Fair Haven	2,004
Newhallville	1,197
West River	881
Edgewood	844
Fair Haven Heights	761
West Rock	758
Annex	706
Dixwell	673
Amity	661
Dwight	652
Quinnipiac Meadows	610
Beaver Hills	514
Wooster Square	374
East Rock	315
Prospect Hill	292
Westville	240
Long Wharf	198
East Shore	132
Downtown	52
Total Unique Patients	14,813

⁴ A sample survey and detailed survey results can be found in the Appendix, pages 34-35.



The 33% of patients that did not use a car are distributed across over 23 neighborhoods, with the largest concentration in the Hill, Fair Haven and Dixwell neighborhoods. Very few PCC patients reside in the Downtown neighborhood, which is closest to the current PCCs, as this is largely a business area.

Transportation Plan Details

The results of the survey, review of patient demographics and review of public and private transportation providers were used to determine the scope and scale of YNHH initiatives around transportation to the 150 Sargent Drive site. ; A majority of patients (over 2/3) utilize private automobiles to access the primary care clinics. For these patients, the 150 Sargent Drive location is approximately 1.5 miles from the YNHH York Street and St. Raphael campuses. It is located off I-91 and I-95, providing easy access by automobile. Consistent with Americans with Disabilities (ADA) guidelines, ample, free parking will be provided for both handicapped and non-handicapped patients, with 250 non-handicapped spaces, 26 handicapped spaces and five spaces for medical vans. The parking lot will be relined to improve drop-off access for patients.

For the 33% of patients utilizing public transportation, walking or using other means of transportation to get to their appointments, YNHH has focused its efforts on ensuring that access for these patients, and/or those who require special transportation assistance will be maintained in a manner that is equal to or better than current services.

Public and private transportation providers that offer services to 150 Sargent Drive include:

- CT Transit
- Greater New Haven Transit District (GNHTD)
- Milford Transit District (MTD)
- Veyo
- Coordinated Transportation Solutions (CTS)
- Uber
- Lyft
- Taxi services
- Section 5310 grantees in the greater New Haven area
- Other non-profits in and around New Haven that offer medical transportation services for specific populations: cancer patients, ALS patients, HIV and AIDs patients, individuals receiving HUSKY D or Military Support Program services, and patients with MS, among others.

YNHH evaluated CT Transit bus routes from the New Haven neighborhoods in which the majority of patients who receive services at the YNHH PCCs live, with special focus on the neighborhoods where the largest concentration of patients not using private vehicles reside. All CT Transit buses have wheelchair lifts or ramps for access by persons with disabilities. Buses can also “kneel” to lower the first step height. According to the CT Transit website: “Most types of mobility devices (wheelchairs, 3-wheel scooters, and walkers) can be accommodated on the buses.”

The 150 Sargent Drive location is served directly by current CT Transit bus routes 274 and 274C, which originate in downtown New Haven. In addition, routes 246 and 241 connect to Route 274, and individuals riding on those routes can stay on the same bus without the need to exit and transfer. All other CT Transit routes in New Haven have connecting stops in downtown New Haven, where individuals are able to transfer to Bus 274/274C to continue on to 150 Sargent Drive.

Senior citizens (65+) and those with a qualifying disability can travel for a reduced fare at any time on CT Transit and all other bus systems operating under contract to the CTDOT.

YNHH and the NHPCC will advocate for a greater number of direct bus routes to 150 Sargent Drive from the New Haven neighborhoods. Although there are many bus stops and frequent bus routes throughout the greater New Haven neighborhoods, many CT Transit bus routes require passengers to change at the New Haven Green, and take a second bus to 150 Sargent Drive. In addition to advocating for more direct bus routes, YNHH will advocate for more frequent routes during “off peak times” to decrease wait times.

The Greater New Haven Transit District (GNHTD) and the Milford Transit District (MTD) are regional providers in Greater New Haven region of ADA-compliant transportation services under Connecticut’s complementary ADA paratransit service. Patients who meet the ADA definition of disability may apply for access to the service on a temporary, conditional or unconditional basis (e.g. those whose disability always prevents them from using public buses need only apply and be certified once for access on all future trips).

YNHH reviewed the special transportation needs of the current PCC patients, and found that 150 patients utilized wheelchairs, and 3 patients required transport via stretcher. This is consistent with national trends found in the Appendix, page 13. These patients are currently enrolled in Veyo and are receiving transportation assistance. No changes are anticipated for these patients when services are relocated.

Medicaid beneficiaries with HUSKY A, C, and D, and limited benefit members that cannot drive themselves, and/or do not have a neighbor, friend, relative, or voluntary organization that can transport them to their appointment are eligible for non-emergency medical transportation (NEMT) assistance, sponsored by the State of Connecticut, currently through a contract with Veyo, which includes a combination of public transportation assistance, ride-share vehicle, wheel-chair accessible vans, and mileage reimbursement, if a family member drives the patient to their appointment.

Coordinated Transportation Solutions (CTS) offers specialized transportation services throughout Connecticut. CTS contracts with three transportation providers operating in and around New Haven, all of which are ADA-compliant and include lift-equipped Handivans, and vehicles with ramps that accommodate powered wheelchairs and scooters.

Section 5310 is a federal grant program intended to improve mobility for seniors and individuals with disabilities by removing barriers to transportation service and expanding transportation mobility options. The Transit Manager of the Bureau of Public Transportation, Connecticut Department of Transportation provided information on Section 5310 grantees in the area that provide medical transportation, including:

- The Kennedy Center,
- Marrakech, Inc.,
- The Mary Wade Home, and
- East Shore Regional Adult Day Center dba Orchard House Medical Adult Day Center.

To the extent that these providers are not adequate to address the transportation needs of the current PCC patients YNHH is contracting with three vendors to provide transportation services: Uber, Milford Transit District (MTD) and Coordinated Transportation Solutions (CTS).⁵

CTS and Uber will provide transportation services for those patients who meet eligibility criteria, and do not require special transportation assistance. Both MTD and CTS will provide ADA-compliant access for those patients who meet eligibility criteria and require this level of transportation assistance.

⁵ YNHH reserves the option to change transportation vendors, as deemed necessary or beneficial, provided those vendors adhere to the same scope of services, eligibility requirements and services standards as current vendors.

Eligibility:

YNHH will offer transportation services, free of charge, to current PCC patients in the Greater New Haven region to 150 Sargent Drive, regardless of financial or insurance status, provided they cannot get to 150 Sargent Drive by car, and meet the following criteria for eligibility for the service:

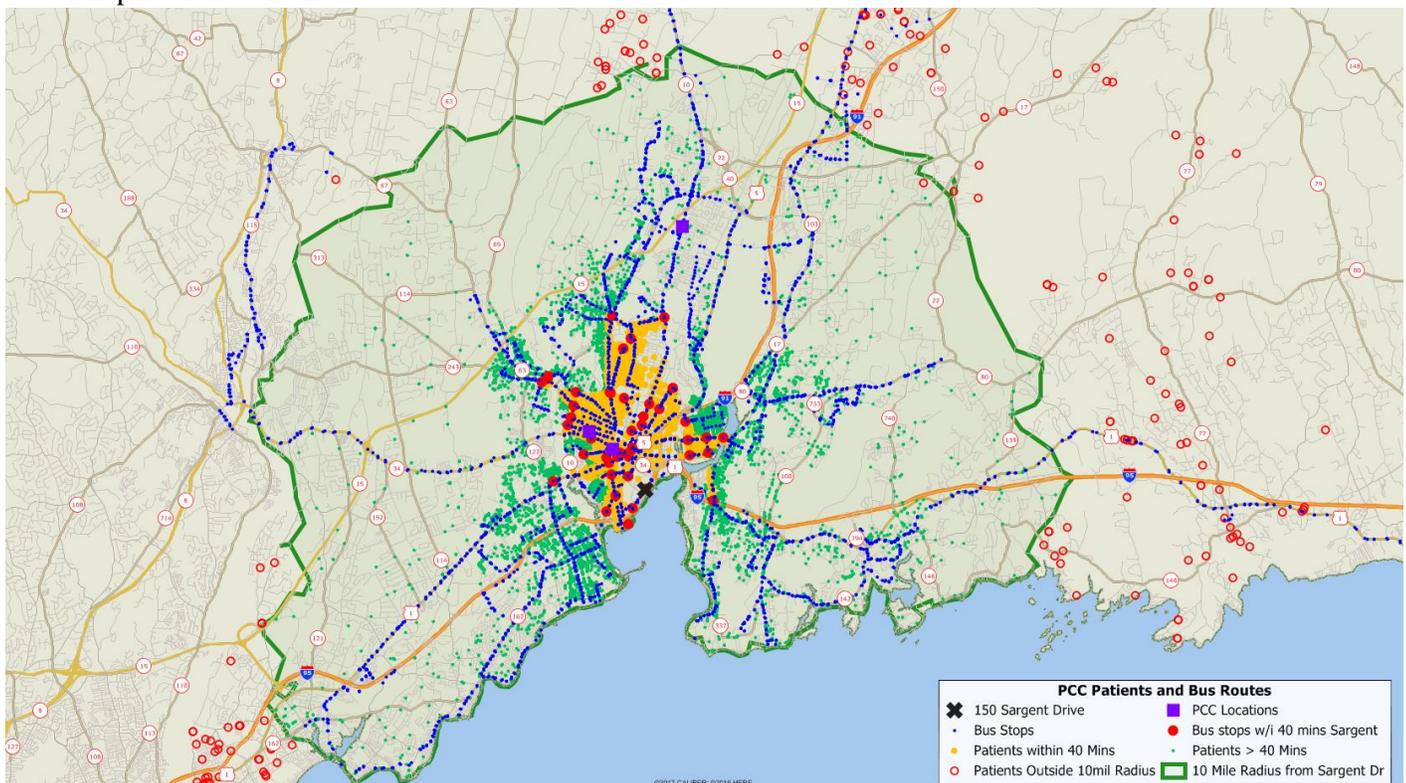
Existing patients of the PCCs, living where currently available public transportation requires a trip of 40 minutes or longer.⁶

For those current PCC patients who require special transportation assistance, and do not qualify for NEMT assistance, YNHH will offer transportation services, free of charge, for patients residing in the Greater New Haven region through MTD and/or CTS.

The map below shows unique patients (as was detailed on page 26) mapped by their street address, with the bus stops and patients located within 40 minutes of Sargent Drive denoted in yellow and red, respectively, and those outside the 40 minute range shown in green for patients and blue for the bus stop locations. The green boundary line denotes a 10 mile radius from 150 Sargent Drive.

The number of unique patients in New Haven living within a 10 mile radius and within 40 minutes by bus of 150 Sargent Drive is 4,484. These patients would not be eligible for transportation services, unless they had special transportation needs and were not eligible for NEMT assistance. For those patients with special transportation needs not eligible for NEMT assistance, YNHH will contract directly with vendors (MTD and CTS) to ensure access for patients requiring ADA-compliant vehicles.

The number of unique patients living within a 10 mile radius, but greater than 40 minutes by bus from 150 Sargent Drive is approximately 9,500 unique patients. These patients would be eligible for transportation services, regardless of insurance or financial status, if they do not have access to a private automobile (e.g. drive themselves or driven by family member or friend) and/or require special transportation assistance.



⁶ The 40 minute time criteria is based on the total time estimate for the trip from publicly available sources.

Contracted Transportation Providers:

CTS and MTD have entered into a Memorandum of Understanding (MOU) with YNHH to provide transportation services consistent with this plan. The signed MOUs are attached on pages 37-52 of the Appendix. Each MOU outlines the scope of transportation services provided, eligibility requirements and service standards. YNHHS has an existing contract with Uber and Uber has agreed to expand its current relationship with YNHHS and has entered into a MOU to that effect. A copy of the Uber MOU is attached in Exhibit 3, pages 53-67 of the Appendix. These vendors will all pick up eligible patients from their homes and transport them to 150 Sargent Drive. In certain instances when required/recommended services can only be accessed at the Hospital campuses, eligible patients will be transported from 150 Sargent Drive to one of the Hospital campus locations.⁷ Patients coming to the hospital from 150 Sargent Drive for required services, other than pharmacy services, may be eligible for rides from the hospital campus back to their homes, on a case-by-case basis, and as determined to be necessary by their physician. All vendors will transport eligible patients from 150 Sargent Drive to their home.

None of the three vendors listed above require use of a smartphone to schedule transportation services. All ride scheduling to and from appointments will be handled by the Health Center office staff.

Scheduling Rides

When an eligible patient requiring transportation assistance calls to schedule an appointment at the Health Center, the staff will also schedule the appropriate transportation for the patient. In addition to scheduling patient transportation for the same day, rides can also be scheduled from seven days to 30 days in advance of the appointment. Upon completion of the appointment, Health Center staff will arrange the return trip. If the patient has access to a smartphone/cell phone, trip confirmations can be sent via text, but in the event the patient does not have a smart phone/cell phone, the Health Center staff will inform patients about their scheduled rides via a phone call or at the end of an appointment. The workflow for the Transportation Plan is attached on page 36 of the Appendix, Exhibit 3.

Service Standards

YNHH has developed service standards for transportation services, including wait times for pick up and drop off, customer service and data tracking. As Uber drivers are independent contractors, Uber maintains Community Guidelines⁸, rather than Service Standards. As applicable, service standards include:

I. Driver standards:

- a) Maintain unrestricted licenses and comply with any and all training requirements of the vendor
- b) Have passed all required background checks
- c) Interact in a professional manner with patients, escorts, attendants, provider and facility staff and any other individuals with whom they come in contact during transportation
- d) Offer assistance to passengers entering or exiting the vehicle as appropriate and upon request
- e) Ensure that infants and children are secured by the parent or guardian using a car seat or booster, if applicable
- f) Secure items such as walkers, strollers or other mobility assistance devices, if applicable
- g) If applicable, ensure that wheelchairs are properly secured to the vehicle during transport
- h) Ensure that passenger's wheelchairs are properly secured in the vehicle, if applicable

⁷ YNHH will continue to provide certain prescription medications to 150 Sargent Drive via courier.

⁸ Uber Community Guidelines are found here: <https://www.uber.com/legal/community-guidelines/us-en/>

II. Vehicle standards:

- a) Complete and maintain record of regular maintenance and safety inspections
- b) Devices in place to secure wheelchairs or other personal mobility devices, as applicable to the vehicles licensed level of service
- c) Capacity to secure child safety seats that meet applicable state and federal guidelines as may be required by State or Federal law.

III. Pick-up/Drop-off standards:

- a) Ensure timely pick-ups. If the transportation provider arrives at the pickup location early or at time of scheduled pick up time, he/she will wait for at least 5 minutes past the scheduled pick up time before declaring the passenger as a no-show.
- b) Ensure timely drop-off for appointments, except for delays outside of the control of Vendor or driver
- c) Requests for service for certified ADA eligible users on a particular day will be accommodated if the reservation is made according to mutually agreeable advance notification.

IV. Customer Service standards:

- a) Maintain a mutually agreed upon mechanism for customer service inquiries and complaints
- b) Accept trip requests by telephone, secure online ordering system, mobile application or other secured electronic means that meet the security requirements defined by HIPAA regulation
- c) Have appropriate policies for responding to complaints
- d) Report on all service standards and complaints to YNHH

Vendors shall report to YNHH, on a schedule to be mutually determined, such information as YNHH may reasonably request, including detailed trip information, which shall include request time and date, pick-up and drop-off time and date, pick-up and drop-off location, trip route, distance, duration, fare amount, service type and any complaints received. YNHH will monitor transportation services provided by Uber via tracking pick-up and drop-off times, and logging patient complaints.

Monitoring of Transportation Plan

YNHH shall track reports provided by vendors on a monthly basis, and if a vendor does not meet the service standards specified, shall be offered 30 day period to remedy the issues. If the issues are not resolved within such 30 day period, YNHH may terminate the relationship.

YNHH commits to conducting a formal evaluation of this plan in partnership with CSHHC and FHCHC following the opening of the 150 Sargent Drive location. Each FQHC will monitor “no show” and late appointments to determine if transportation was a factor, as well as survey patients. Any adjustments to the plan will be made on the basis of these evaluations, on a bi-annual basis.

Appendix

Transportation Survey



Thank you for taking this transportation survey. We hope to better understand your needs. All answers will be kept confidential.

How did you get here today?

- Bus
 Car - Drove Myself
 Car - Dropped Off
 Medical Taxi
 Taxi/Uber/Lyft
 Walked
 Other _____

Is this the normal way you get here? Yes No

If no, what is normal for you? _____

How will you get home today?

- Bus
 Car - Drive Myself
 Car - Picked Up
 Medical Taxi
 Taxi/Uber/Lyft
 Walked
 Other _____

(Optional) What neighborhood are you coming from?

- Amity Beaver Hills Dixwell Downtown Dwight East Rock
 Edgewood Fair Haven Fair Haven Heights Hill Long Wharf Mill River
 Newhallville Prospect Hill Quinnipiac Meadows West River West Rock Westville
 Yale Other _____

Have you ever missed a medical visit because of transportation costs? Yes No

If yes, please select all that apply: Bus Cost Gas Cost Parking Cost

Other (please specify) _____

Thank you!

13873 (06/18)

Survey Results:

Transportation Survey Respondents By Clinic										
Transportation Method	Clinic									Transportation Method as a % of Total
	Chapel Pediatrics	SRC Adult	SRC Pediatrics	SRC WIC	YSC Adult	YSC Pediatrics	YSC WIC	YSC Women's	Total All Clinics	
Car - Drove Myself	291	123	197	59	113	153	118	127	1,181	47%
Car - Dropped Off	24	71	48	19	81	70	67	91	471	19%
Bus	9	61	40	9	62	48	65	70	364	15%
Walked	2	48	33	17	51	48	27	30	256	10%
Medical Taxi	2	29	3	1	30	31		16	112	4%
Taxi/Uber/Lyft	6	8	5	2	20	11	11	19	82	3%
Other (1)	3	14	1	2	6	2	2	4	34	1%
Total All Methods	337	354	327	109	363	363	290	357	2,500	100%
% By Bus	3%	14%			18%			15%		
% Walked	1%	12%			11%			10%		
Campus	Chapel Pediatrics	Saint Raphael Campus			York Street Campus			Total All Clinics		

(1) Other method of transportation (n=20) or no response (n= 14)

Transportation Survey Respondents By Neighborhood (Part 1)										
Transportation Method	Neighborhood									
	Fair Haven	Dixwell	Hill	Edgewood	Newhall-ville	Westville	Fair Haven Heights	Amity	Quinnipiac Meadows	Down-town
Car - Drove Myself	111	107	70	45	52	48	45	36	40	14
Car - Dropped Off	55	50	37	20	19	21	20	8	15	10
Bus	62	42	12	13	22	17	14	25	12	19
Walked	8	13	72	27	4	2	1	1		18
Medical Taxi	9	14	18	2	3	2	6		2	7
Taxi/Uber/Lyft	3	9	7	2	3	3	9	1	2	3
Other (1)	3		3		1	2		1	1	
Total All Methods	251	235	219	109	104	95	95	72	72	71
% By Bus	25%	18%	5%	12%	21%	18%	15%	35%	17%	27%
% Walked	3%	6%	33%	25%	4%	2%	1%	1%	0%	25%

(1) Other method of transportation (n=20) or no response (n= 14)

Transportation Survey Respondents By Neighborhood (Part 2)										
Transportation Method	Neighborhood									Total All Neighborhoods
	Yale	Beaver Hills	Dwight	West River	East Rock	Long Wharf	Prospect Hill	West Rock	Other (2)	
Car - Drove Myself	17	23	7	10	14	11	11	14	506	1,181
Car - Dropped Off	11	2	4	6	5	3	6	4	175	471
Bus	4	10	2	2	4	2	2	4	96	364
Walked	26	3	17	11	1	1	1		50	256
Medical Taxi	4	1	2	2	1	4	2		33	112
Taxi/Uber/Lyft			2		3	5	1	1	28	82
Other (1)				2		1			20	34
Total All Methods	62	39	34	33	28	27	23	23	908	2,500
% By Bus	6%	26%	6%	6%	14%	7%	9%	17%	11%	15%
% Walked	42%	8%	50%	33%	4%	4%	4%	0%	6%	10%

(1) Other method of transportation (n=20) or no response (n= 14)

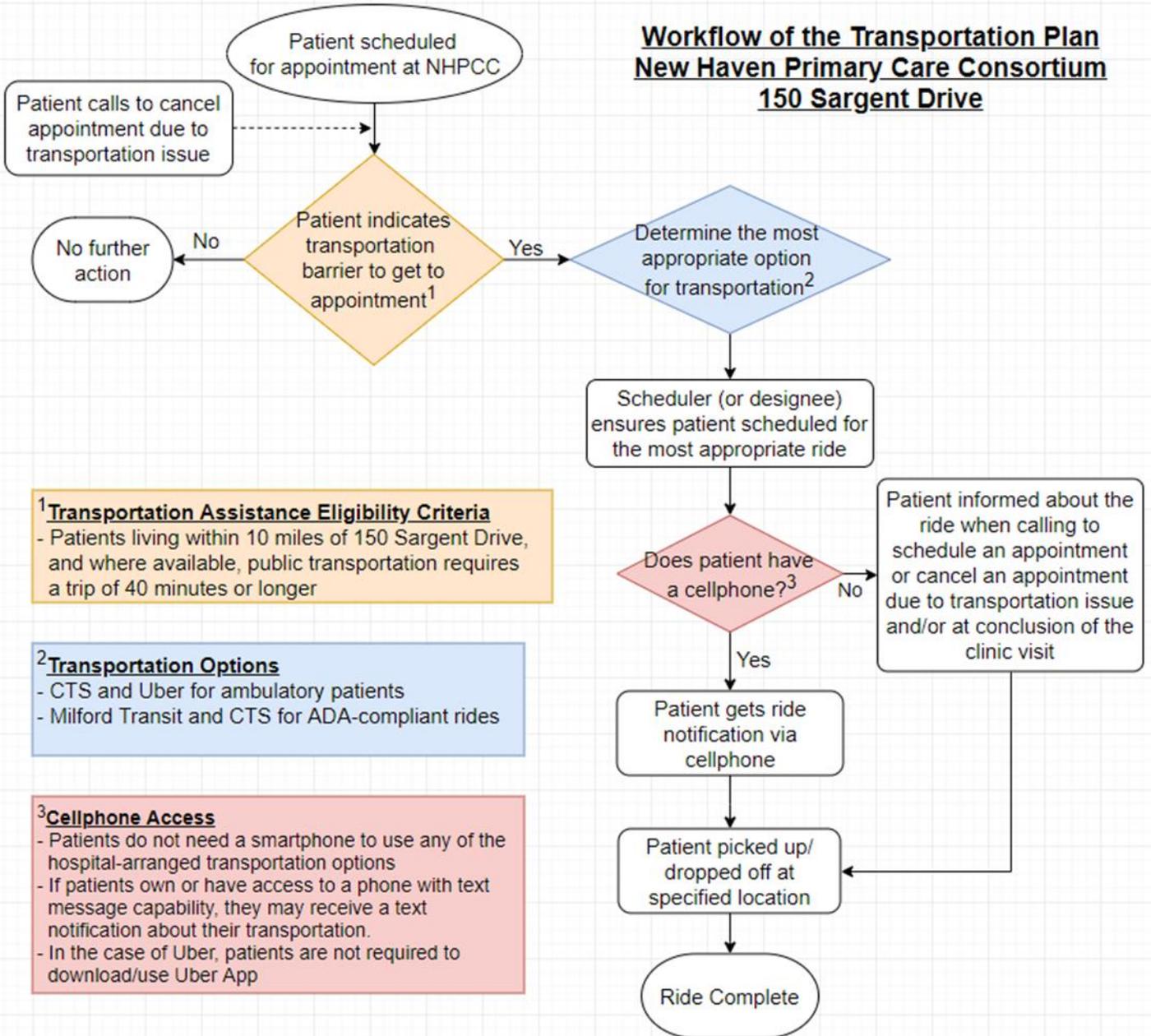
(2) Other New Haven neighborhoods (n=14), town/neighborhood not specified (n=724), or no response (n= 171)

National Benchmarks for Assisted Transportation

	Mobility Device	US Population	% US Population
Any Assist Device	6,800,000	327,000,000	2%
Wheelchair/Scooter	1,700,000	327,000,000	0.5%
Canes, crutches, walkers	6,100,000	327,000,000	1.9%

<https://www.disabled-world.com/disability/statistics/mobility-stats.php>

Workflow of the Transportation Plan
New Haven Primary Care Consortium
150 Sargent Drive



May 13, 2019

MEMORANDUM OF UNDERSTANDING

THIS MEMORANDUM OF UNDERSTANDING ("**MOU**"), dated as of May 2^o 2019, is by and between **YALE-NEW HAVEN HOSPITAL, INC.**, a Connecticut nonstock corporation with an address of 20 York Street, New Haven, Connecticut 06510 ("**YNHH**") and Milford Transit District, a public non-profit transportation district with an address of 259 Research Drive, Milford, CT 06460 ("**Vendor**") (YNHH and Vendor are referred to collectively as the "**Parties**" and individually as a "**Party**").

WITNESSETH

WHEREAS, YNHH is a member of the New Haven Primary Care Consortium (the "**NHPCC**"), an unincorporated association of health care providers in New Haven providing primary care and related services to patients in the Greater New Haven Community; and

WHEREAS, in addition to YNHH, the NHPCC includes, as members, two local federally-qualified health centers, Cornell-Scott Hill Health Center and Fair Haven Community Health Center (the "**Health Centers**"); and

WHEREAS, YNHH intends to transition its existing primary care clinics to the Health Centers; and

WHEREAS, in connection with the transition, YNHH will renovate the building known as 150 Sargent Drive in New Haven (the "**150 Sargent Drive Site**") into an integrated site at which the two Health Centers will provide primary care and YNHH will offer ancillary health services; and

WHEREAS, YNHH will continue to provide certain ancillary services not offered at the 150 Sargent Drive Site at its main campus locations, 20 York Street and 1450 Chapel Street (the "**Hospital Campus Locations**"); and

WHEREAS, the relocation of primary care services to the 150 Sargent Drive Site will provide many benefits to patients; and

WHEREAS, in recognition of the fact that a number of the patients of the primary care centers currently rely on public transportation and or face other transportation barriers to care, YNHH wishes to contract with Vendor to provide transportation services to the 150 Sargent Drive Site and to other locations, on the general terms set forth herein.

NOW, THEREFORE, the Parties agree as follows:

1. **Agreement**. The Parties agree to use commercially reasonable efforts to negotiate the terms of a definitive services agreement (the "**Definitive Agreement**") pursuant to which Vendor will provide transportation services for Eligible Patients (as hereinafter defined). Transportation services will be limited to travel (i) from the home of the Eligible Patient to the 150 Sargent Drive Site; (ii) from the Sargent Drive Site to a Hospital Campus Location in certain instances when required/recommended services can only be accessed at the Hospital Campus Location; and (iii) from the Eligible Patient's final destination (either the 150 Sargent Drive Site or one of the Hospital Campus Locations) to the Eligible

Patient's home. "Eligible Patients" shall mean patients of YNHH or either of the health centers located at the 150 Sargent Drive Site who (i) are not eligible for a State-sponsored ride service; and (ii) rely on public transportation and for whom travel to Sargent Drive requires travel time of greater than forty minutes or require specialized paratransit services as a result of a disability recognized under the Americans with Disabilities Act (the "ADA").

2. **Conflicting Arrangements.** Each Party hereby represents and warrants for itself and its affiliates that it is not a party to nor subject to any agreement, instrument, law, statute, proceeding or order that would prevent or impede its ability to enter into and consummate the Definitive Agreement.

3. **Vendor Obligations.** The Definitive Agreement shall include, at a minimum, the following obligations of Vendor:

(a) Vendor shall maintain a transportation network with qualified drivers and fleet sufficient to ensure that transportation needs of Eligible Patients are satisfied;

(b) Vendor shall maintain a mutually agreed upon contact mechanism for customers (e.g., call center or other customer service contact) that operates during normal business hours for all customer service inquiries, including complaints;

(c) Vendor will provide adequate training, customer service and technical support to authorized YNHH/NHPCC staff responsible for scheduling the transportation rides to/from the 150 Sargent Drive Site and/or the Hospital Campus Locations;

(d) Vendor shall ensure that its fleet includes sufficient number of vehicles that can provide ADA-compliant services to patients who require specialized paratransit services as a result of a disability recognized under the ADA and shall ensure that all drivers are appropriately trained to assist patients, based on patient need; and

(e) Vendor shall comply with the service standards set forth in Exhibit A.

4. **Other Terms.** The Parties agree that the Definitive Agreement shall include the following additional terms:

(a) The Parties acknowledge that the plans with respect to the 150 Sargent Drive Site may not be implemented without first obtaining certain regulatory approvals. The Parties will use reasonable best efforts to finalize and execute the Definitive Agreement at least three (3) months prior to the planned implementation date (the "***Implementation Date***"). The Definitive Agreement will have a term of three (3) years from the Implementation Date, subject to early termination for breach.

(b) Vendor will ensure that a master account is established for YNHH pursuant to which all charges for transportation services under the Definitive Agreement will be paid by YNHH and no charges will be made to any Eligible Patient. The financial terms of the arrangement will be mutually

agreed upon by the Parties; provided that YNHH shall not be charged more than Vendor's standard transportation charges.

(c) Vendor will agree to provide all services in accordance with all applicable laws and regulations and best industry standards.

(d) Vendor shall report to YNHH, on a schedule to be mutually determined, such information as YNHH may reasonably request, including detailed trip information, which shall include request time and date, pick-up and drop-off time and date, pick-up and drop-off location, trip route, distance, duration, fare amount, service type and any complaints received.

(e) Vendor will provide standard representations and covenants to YNHH, including annual confirmation that neither Vendor nor any employee or agent performing services under the Definitive Agreement has ever been (1) convicted of a criminal offense related to health care and/or related to the provision of services paid for by Medicare, Medicaid or another federal health care program; (2) excluded or debarred from participation in any federal health care program, including Medicare and Medicaid; or (3) otherwise sanctioned by the federal government, including being listed on the General Services Administration's Excluded Party Listing System.

(f) Vendor shall maintain appropriate insurance coverage consistent with YNHH's vendor standards, including commercial general liability, workers' compensation and commercial automobile liability, all by an insurer with an A.M. Best financial rating of "A-" or better.

(g) If and to the extent that any protected health information is to be shared with Vendor in connection with its services, Vendor shall enter into YNHH's standard form Business Associate Agreement and shall comply with the terms thereof.

5. **Confidentiality.** Each Party agrees that it will not disclose any "**Proprietary Information**" (as defined in this Section) that it receives in the course of negotiating the Definitive Agreement and performing under this MOU except as is reasonably necessary for the purposes of entering into the Definitive Agreement, and it will not use Proprietary Information except for the entering into and consummating the terms of the Definitive Agreement. Each Party shall treat as confidential the Proprietary Information of the other Party and shall each use its best efforts to hold the Proprietary information of the other Party in strict confidence. A Party shall only disclose Proprietary Information received from the other Party to its representatives who need to know the Proprietary Information for the purpose of the Definitive Agreement, who are informed of the confidential nature of the Proprietary Information, and who agree to be bound by the terms of this MOU. Each Party receiving Proprietary Information shall use due care to prevent its representatives from disclosing the Proprietary Information and shall be liable to the other party for any damages caused by the breach of this provision by its representatives.

If a Party or a Party's representative is requested or required by any governmental authority to disclose the Proprietary Information of the other Party, it shall provide the other Party with prompt written notice of the request or demand, so the other Party may seek an appropriate protective

order. No Party shall be liable for the disclosure of Proprietary Information if said disclosure is required by law or order of an appropriate administrative agency.

For the purposes of this MOU, "**Proprietary Information**" shall include all tangible and intangible information which is related in any way to the Definitive Agreement, the 150 Sargent Drive Site and its operations, or the NHPCC and is of a confidential or proprietary nature, including but not limited to, analyses, business or strategic plans, compilations, financial statements, proposals, studies, patient revenue, gross charges, payor mix, employment or compensation models or other information relating to the business of a party or any of its corporate affiliates.

6. **Term and Termination.**

(a) This MOU shall commence on the date hereof and continue until terminated as provided herein.

(b) This MOU shall terminate automatically:

(i) upon the mutual agreement of the Parties; or

(iii) upon execution of the Definitive Agreement.

(c) This MOU may be terminated by either Party:

(i) if a default exists in the due observance of any of the covenants or agreements by any Party set forth herein; provided, however that such right of termination shall only apply if written notice of such default has been given and the defaulting party has not cured such default within thirty (30) days of receipt of such notice; or

(ii) if the conditions precedent for the Implementation Date referenced in Section 4 above have not been satisfied by December 31, 2020.

7. **Public Communications.** No public announcement regarding this MOU shall be made unless the Parties have mutually agreed in writing on the content and timing of such announcement. The Parties recognize, however, that the substance of this MOU will, in fact, be disclosed to the Office of Health Strategy as part of the Certificate of Need application in connection with the NHPCC.

8. **Enforceability.** This MOU reflects our mutual understanding of the matters described herein, but each party acknowledges that this MOU is not intended to create or constitute any legally binding obligation among the parties hereto with respect to the provision of transportation services unless and until a Definitive Agreement is prepared, authorized, executed and/or delivered by and between the parties. If a Definitive Agreement is not prepared, authorized, executed, and/or delivered for any reason, no party to this MOU shall have liability to any other party to this MOU based upon or relating to this MOU, other than obligations in connection with Sections 5, 6, 7, 8 and 9 hereof, which shall be binding.

9. **Miscellaneous.**

(a) This MOU shall be governed by the laws of the State of Connecticut.

(b) This MOU shall not be amended or otherwise modified except by a written amendment duly executed by authorized representatives of both Parties.

(c) The failure of either Party hereto to insist upon strict adherence to any provision of this MOU on any occasion shall not be considered a waiver of such Party's right to insist upon strict adherence to such provision on any other occasion or to any other provision of this MOU in any instance. Any waiver shall be in writing signed by a duly authorized representative of the Party against whom such waiver is sought to be enforced.

(d) If one or more provisions of this MOU is found by an arbitrator or court of competent jurisdiction to be illegal, invalid or unenforceable in whole or in part, the remaining terms and provisions of this MOU shall remain in full force and effect disregarding such illegal, invalid or unenforceable portion and such arbitrator or court shall be empowered to modify, if possible, such unenforceable provision to the extent necessary to make this MOU enforceable in accordance with the intent and purposes of the Parties expressed herein to the fullest extent permitted by applicable law.

(e) The section headings contained in this MOU are for convenience only and they in no way define, limit or enlarge the scope of the provisions of such sections and shall not be considered in the interpretation or enforcement of this MOU.

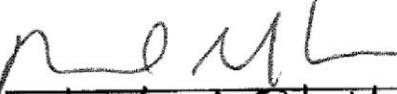
(f) This MOU shall be deemed to have been drafted jointly by the Parties hereto and no presumption or rules of construction based upon the drafting of this MOU shall be made in any arbitration or legal proceedings arising hereunder.

[Signature page follows.]

IN WITNESS WHEREOF, the parties hereto have caused this MOU to be signed by their duly authorized officers as of the day and year first above written.

YALE-NEW HAVEN HOSPITAL, INC.

[VENDOR]

By: 
Name: Michael Schaffer
Title: VP, Ambulatory Care

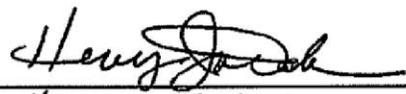
By: 
Name: HENRY JACH
Title: Exec. Director

EXHIBIT A

Service Standards

I. Driver standards:

- a) Interact in a professional manner with patients, escorts, attendants, provider and facility staff and any other individuals with whom they come in contact during transportation
- b) Be clean and maintain a neat appearance at all times
- c) Properly identify and make their presence known at the specified pick-up location
- d) Offer assistance to passengers entering or exiting the vehicle as needed and upon request
- e) Ensure that infants and children are secured in a car seat by the parent or guardian using a seat or booster
- f) Secure items such as walkers, strollers or other mobility assistance devices
- g) If applicable, ensure that wheelchairs are properly secured to the vehicle during transport
- h) Ensure that passengers in wheelchairs are properly secured in their chairs
- i) Maintain unrestricted licenses and comply with any and all training requirements of Vendor
- j) Have passed all required background checks

II. Vehicle standards:

- a) Complete and maintain record of regular maintenance and safety inspections
- b) Clean exteriors that are free of broken mirrors or windows, excessive grime, rust, chipped paint or major dents that detract from the overall appearance of the vehicle
- c) Clean Interiors that are free from torn upholstery or floor covering, damaged or broken seats, protruding sharp edges and free of dirt, oil, grease or litter
- d) Devices in place to secure wheelchairs or other personal mobility devices, as applicable to the vehicles licensed level of service
- e) Capacity to secure child safety seats that meet applicable state and federal guidelines as may be required by State or Federal law

III. Customer Service standards:

- a) Maintain a mutually agreed upon customer service mechanism
- b) Accept trip requests by telephone, secure online ordering system, mobile application or other secured electronic means that meet the security requirements defined by HIPAA regulation
- c) Have appropriate policies for responding to complaints
- d) Report on all service standards and complaints to YNHH

IV. Pick-up/Drop-off standards:

- a) Ensure timely pick ups. If the transportation provider arrives at the pickup location early or at time of scheduled pick up time, he/she will wait for at least 5 minutes before declaring the passenger as a no-show
- b) Ensure timely drop-off for appointments, except for delays outside of the control of Vendor or driver
- c) Requests for service for certified ADA eligible users on a particular day will be accommodated if the reservation is made according to mutually agreeable advance notification

May 13, 2019

MEMORANDUM OF UNDERSTANDING

THIS MEMORANDUM OF UNDERSTANDING ("**MOU**"), dated as of May 20, 2019, is by and between **YALE-NEW HAVEN HOSPITAL, INC.**, a Connecticut nonstock corporation with an address of 20 York Street, New Haven, Connecticut 06510 ("**YNHH**") and Coordinated Transportation Solutions, Inc., a not-for-profit 501(c)3 organization with an address of 35 Nutmeg Drive, Suite 120, Trumbull, CT 06611 ("**Vendor**") (YNHH and Vendor are referred to collectively as the "**Parties**" and individually as a "**Party**").

WITNESSETH

WHEREAS, YNHH is a member of the New Haven Primary Care Consortium (the "**NHPCC**"), an unincorporated association of health care providers in New Haven providing primary care and related services to patients in the Greater New Haven Community; and

WHEREAS, in addition to YNHH, the NHPCC includes, as members, two local federally-qualified health centers, Cornell-Scott Hill Health Center and Fair Haven Community Health Center (the "**Health Centers**"); and

WHEREAS, YNHH intends to transition its existing primary care clinics to the Health Centers; and

WHEREAS, in connection with the transition, YNHH will renovate the building known as 150 Sargent Drive in New Haven (the "**150 Sargent Drive Site**") into an integrated site at which the two Health Centers will provide primary care and YNHH will offer ancillary health services; and

WHEREAS, YNHH will continue to provide certain ancillary services not offered at the 150 Sargent Drive Site at its main campus locations, 20 York Street and 1450 Chapel Street (the "**Hospital Campus Locations**"); and

WHEREAS, the relocation of primary care services to the 150 Sargent Drive Site will provide many benefits to patients; and

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NOW, THEREFORE, the Parties agree as follows:

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destination (either the 150 Sargent Drive Site or one of the Hospital Campus Locations) to the Eligible Patient's home. "Eligible Patients" shall mean patients of YNHH or either of the health centers located at the 150 Sargent Drive Site who (i) are not eligible for a State-sponsored ride service; and (ii) rely on public transportation and for whom travel to Sargent Drive requires travel time of greater than forty minutes or require specialized paratransit services as a result of a disability recognized under the Americans with Disabilities Act (the "ADA").

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(d) Vendor shall ensure that its fleet includes sufficient number of vehicles that can provide ADA-compliant services to patients who require specialized paratransit services as a result of a disability recognized under the ADA and shall ensure that all drivers are appropriately trained to assist patients, based on patient need; and

(e) Vendor shall comply with the service standards set forth in Exhibit A.

4. **Other Terms.** The Parties agree that the Definitive Agreement shall include the following additional terms:

(a) The Parties acknowledge that the plans with respect to the 150 Sargent Drive Site may not be implemented without first obtaining certain regulatory approvals. The Parties will use reasonable best efforts to finalize and execute the Definitive Agreement at least three (3) months prior to the planned implementation date (the "***Implementation Date***"). The Definitive Agreement will have a term of three (3) years from the Implementation Date, subject to early termination for breach.

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agreed upon by the Parties; provided that YNHH shall not be charged more than Vendor's standard transportation charges.

(c) Vendor will agree to provide all services in accordance with all applicable laws and regulations and best industry standards.

(d) Vendor shall report to YNHH, on a schedule to be mutually determined, such information as YNHH may reasonably request, including detailed trip information, which shall include request time and date, pick-up and drop-off time and date, pick-up and drop-off location, trip route, distance, duration, fare amount, service type and any complaints received.

(e) Vendor will provide standard representations and covenants to YNHH, including annual confirmation that neither Vendor nor any employee or agent performing services under the Definitive Agreement has ever been (1) convicted of a criminal offense related to health care and/or related to the provision of services paid for by Medicare, Medicaid or another federal health care program; (2) excluded or debarred from participation in any federal health care program, including Medicare and Medicaid; or (3) otherwise sanctioned by the federal government, including being listed on the General Services Administration's Excluded Party Listing System.

(f) Vendor shall maintain appropriate insurance coverage consistent with YNHH's vendor standards, including commercial general liability, workers' compensation and commercial automobile liability, all by an insurer with an A.M. Best financial rating of "A-" or better.

(g) If and to the extent that any protected health information is to be shared with Vendor in connection with its services, Vendor shall enter into YNHH's standard form Business Associate Agreement and shall comply with the terms thereof.

5. **Confidentiality**. Each Party agrees that It will not disclose any "***Proprietary Information***" (as defined in this Section) that it receives in the course of negotiating the Definitive Agreement and performing under this MOU except as is reasonably necessary for the purposes of entering into the Definitive Agreement, and It will not use Proprietary Information except for the entering into and consummating the terms of the Definitive Agreement. Each Party shall treat as confidential the Proprietary Information of the other Party and shall each use its best efforts to hold the Proprietary information of the other Party in strict confidence. A Party shall only disclose Proprietary Information received from the other Party to its representatives who need to know the Proprietary Information for the purpose of the Definitive Agreement, who are informed of the confidential nature of the Proprietary Information, and who agree to be bound by the terms of this MOU. Each Party receiving Proprietary Information shall use due care to prevent its representatives from disclosing the Proprietary Information and shall be liable to the other party for any damages caused by the breach of this provision by its representatives.

If a Party or a Party's representative is requested or required by any governmental authority to disclose the Proprietary Information of the other Party, it shall provide the other Party with prompt written notice of the request or demand, so the other Party may seek an appropriate protective

order. No Party shall be liable for the disclosure of Proprietary Information if said disclosure is required by law or order of an appropriate administrative agency.

For the purposes of this MOU, "**Proprietary Information**" shall include all tangible and intangible information which is related in any way to the Definitive Agreement, the 150 Sargent Drive Site and its operations, or the NHPCC and is of a confidential or proprietary nature, including but not limited to, analyses, business or strategic plans, compilations, financial statements, proposals, studies, patient revenue, gross charges, payor mix, employment or compensation models or other information relating to the business of a party or any of its corporate affiliates.

6. **Term and Termination.**

(a) This MOU shall commence on the date hereof and continue until terminated as provided herein.

(b) This MOU shall terminate automatically:

(i) upon the mutual agreement of the Parties; or

(iii) upon execution of the Definitive Agreement.

(c) This MOU may be terminated by either Party:

(i) if a default exists in the due observance of any of the covenants or agreements by any Party set forth herein; provided, however that such right of termination shall only apply if written notice of such default has been given and the defaulting party has not cured such default within thirty (30) days of receipt of such notice; or

(ii) if the conditions precedent for the Implementation Date referenced in Section 4 above have not been satisfied by December 31, 2020.

7. **Public Communications.** No public announcement regarding this MOU shall be made unless the Parties have mutually agreed in writing on the content and timing of such announcement. The Parties recognize, however, that the substance of this MOU will, in fact, be disclosed to the Office of Health Strategy as part of the Certificate of Need application in connection with the NHPCC.

8. **Enforceability.** This MOU reflects our mutual understanding of the matters described herein, but each party acknowledges that this MOU is not intended to create or constitute any legally binding obligation among the parties hereto with respect to the provision of transportation services unless and until a Definitive Agreement is prepared, authorized, executed and/or delivered by and between the parties. If a Definitive Agreement is not prepared, authorized, executed, and/or delivered for any reason, no party to this MOU shall have liability to any other party to this MOU based upon or relating to this MOU, other than obligations in connection with Sections 5, 6, 7, 8 and 9 hereof, which shall be binding.

9. **Miscellaneous.**

(a) This MOU shall be governed by the laws of the State of Connecticut.

(b) This MOU shall not be amended or otherwise modified except by a written amendment duly executed by authorized representatives of both Parties.

(c) The failure of either Party hereto to insist upon strict adherence to any provision of this MOU on any occasion shall not be considered a waiver of such Party's right to insist upon strict adherence to such provision on any other occasion or to any other provision of this MOU in any instance. Any waiver shall be in writing signed by a duly authorized representative of the Party against whom such waiver is sought to be enforced.

(d) If one or more provisions of this MOU is found by an arbitrator or court of competent jurisdiction to be illegal, invalid or unenforceable in whole or in part, the remaining terms and provisions of this MOU shall remain in full force and effect disregarding such illegal, invalid or unenforceable portion and such arbitrator or court shall be empowered to modify, if possible, such unenforceable provision to the extent necessary to make this MOU enforceable in accordance with the intent and purposes of the Parties expressed herein to the fullest extent permitted by applicable law.

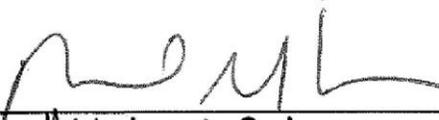
(e) The section headings contained in this MOU are for convenience only and they in no way define, limit or enlarge the scope of the provisions of such sections and shall not be considered in the interpretation or enforcement of this MOU.

(f) This MOU shall be deemed to have been drafted jointly by the Parties hereto and no presumption or rules of construction based upon the drafting of this MOU shall be made in any arbitration or legal proceedings arising hereunder.

[Signature page follows.]

IN WITNESS WHEREOF, the parties hereto have caused this MOU to be signed by their duly authorized officers as of the day and year first above written.

YALE-NEW HAVEN HOSPITAL, INC.

By: 
Name: Michael Schaffer
Title: VP, Ambulatory Care

[VENDOR]

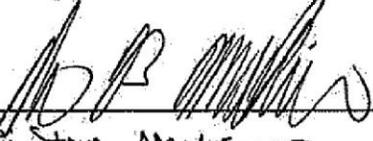
By: 
Name: Steve Mackinnon
Title: Vice President, Administration

EXHIBIT A

Service Standards**I. Driver standards:**

- a) Interact in a professional manner with patients, escorts, attendants, provider and facility staff and any other individuals with whom they come in contact during transportation
- b) Be clean and maintain a neat appearance at all times
- c) Properly identify and make their presence known at the specified pick-up location
- d) Offer assistance to passengers entering or exiting the vehicle as needed and upon request
- e) Ensure that infants and children are secured in a car seat by the parent or guardian using a seat or booster
- f) Secure items such as walkers, strollers or other mobility assistance devices
- g) If applicable, ensure that wheelchairs are properly secured to the vehicle during transport
- h) Ensure that passengers in wheelchairs are properly secured in their chairs
- i) Maintain unrestricted licenses and comply with any training requirements of Vendor
- j) Have passed all required background checks

II. Vehicle standards:

- a) Complete and maintain record of regular maintenance and safety inspections
- b) Clean exteriors that are free of broken mirrors or windows, excessive grime, rust, chipped paint or major dents that detract from the overall appearance of the vehicle
- c) Clean interiors that are free from torn upholstery or floor covering, damaged or broken seats, protruding sharp edges and free of dirt, oil, grease or litter
- d) Devices in place to secure wheelchairs or other personal mobility devices, as applicable to the vehicles licensed level of service
- e) Capacity to secure child safety seats that meet applicable state and federal guidelines as may be required by State or Federal law

III. Customer Service standards:

- a) Maintain a mutually agreed upon mechanism for customer service inquiries and complaints
- b) Accept trip requests by telephone, secure online ordering system, mobile application or other secured electronic means that meet the security requirements defined by HIPAA regulation
- c) Have appropriate policies for responding to complaints
- d) Report on all service standards and complaints to YNHH

IV. Pick-up/Drop-off standards:

- a) Ensure timely pick ups. If the transportation provider arrives at the pickup location early or at time of scheduled pick up time, he/she will wait for at least 5 minutes before declaring the passenger as a no-show
- b) Ensure timely drop-off for appointments, except for delays outside of the control of Vendor or driver
- c) Requests for service for certified ADA eligible users on a particular day will be accommodated if the reservation is made according to mutually agreeable advance notification.

May 13, 2019

MEMORANDUM OF UNDERSTANDING

THIS MEMORANDUM OF UNDERSTANDING ("*MOU*"), dated as of the date of the last signature set forth below, is by and between **YALE-NEW HAVEN HOSPITAL, INC.**, a Connecticut nonstock corporation with an address of 20 York Street, New Haven, Connecticut 06510 ("*YNHH*") and Uber Health, a Delaware limited liability company with an address of 1455 Market Street, Suite 400, San Francisco, CA 94103 ("*Vendor*") (YNHH and Vendor are referred to collectively as the "*Parties*" and individually as a "*Party*").

WITNESSETH

WHEREAS, YNHH is a member of the New Haven Primary Care Consortium (the "*NHPCC*"), an unincorporated association of health care providers in New Haven providing primary care and related services to patients in the Greater New Haven Community; and

WHEREAS, in addition to YNHH, the NHPCC includes, as members, two local federally-qualified health centers, Cornell-Scott Hill Health Center and Fair Haven Community Health Center (the "*Health Centers*"); and

WHEREAS, YNHH intends to transition its existing primary care clinics to the Health Centers; and

WHEREAS, in connection with the transition, YNHH will renovate the building known as 150 Sargent Drive in New Haven (the "*150 Sargent Drive Site*") into an integrated site at which the two Health Centers will provide primary care and YNHH will offer ancillary health services; and

WHEREAS, YNHH will continue to provide certain ancillary services not offered at the 150 Sargent Drive Site at its main campus locations, 20 York Street and 1450 Chapel Street (the "*Hospital Campus Locations*"); and

WHEREAS, the relocation of primary care services to the 150 Sargent Drive Site will provide many benefits to patients; and

WHEREAS, Uber Health or its Affiliates offer a technology service that enables users to request on-demand ground transportation and logistics services from independent third-party providers (the "*Uber Service*");

WHEREAS, in recognition of the fact that a number of the patients of the primary care centers currently rely on public transportation and or face other transportation barriers to care, YNHH wishes to contract with Vendor to provide the Uber Service to the 150 Sargent Drive Site and to other locations, on the general terms set forth herein.

NOW, THEREFORE, the Parties agree as follows:

1. **Agreement.** The Parties agree to use commercially reasonable efforts to negotiate the terms of a definitive services agreement (the "*Definitive Agreement*") pursuant to which Vendor will

provide the Uber Service for Eligible Patients (as hereinafter defined). The use of the Uber Service will be limited to travel via ambulatory sedans (i) from the home of the Eligible Patient to the 150 Sargent Drive Site; (ii) from the Sargent Drive Site to a Hospital Campus Location in certain instances when required/recommended services can only be accessed at the Hospital Campus; and (iii) from the Eligible Patient's final destination (either the 150 Sargent Drive Site or one of the Hospital Campus Locations) to the Eligible Patient's home. "Eligible Patients" shall mean patients of YNHH or either of the health centers located at the 150 Sargent Drive Site who (i) are not eligible for a State-sponsored ride service; and (ii) rely on public transportation and for whom travel to Sargent Drive requires travel time of greater than forty minutes.

2. **Conflicting Arrangements.** Each Party hereby represents and warrants for itself and its affiliates that it is not a party to nor subject to any agreement, instrument, law, statute, proceeding or order that would prevent or impede its ability to enter into and consummate the Definitive Agreement.

3. **Vendor Obligations.** The Definitive Agreement shall include, at a minimum, the following obligations of Vendor:

(a) Vendor shall provide the Uber Service to meet transportation needs of Eligible Patients;

(b) Vendor will provide adequate training, customer service and technical support to authorized YNHH/NHPCC staff responsible for scheduling the transportation rides to/from 150 Sargent Drive and/or the Hospital campuses

(c) Vendor shall comply with the service standards set forth in Exhibit A.

4. **Other Terms.** The Parties agree that the Definitive Agreement shall include the following additional terms:

(a) The Parties acknowledge that the plans with respect to the 150 Sargent Drive Site may not be implemented without first obtaining certain regulatory approvals. The Parties will use reasonable best efforts to finalize and execute the Definitive Agreement at least three (3) months prior to the planned implementation date (the "***Implementation Date***"). The Definitive Agreement will have a term of three (3) years from the Implementation Date, subject to termination provisions agreed to in the Definitive Agreement.

(b) Vendor will ensure that an account is established for YNHH pursuant to which all charges for transportation services under the Definitive Agreement will be paid by YNHH and no charges will be made to any Eligible Patient. The financial terms of the arrangement will be mutually agreed upon by the Parties; provided that YNHH shall not be charged more than Vendor's standard transportation charges.

(c) Vendor will agree to provide all services in accordance with all applicable laws and regulations.

(d) Vendor shall report to YNHH, on a schedule to be mutually determined, such information as YNHH may reasonably request, including detailed trip information, which shall include request time and date, pick-up and drop-off time and date, pick-up and drop-off location, trip route, distance, duration, fare amount, and service type.

(e) Vendor will provide standard representations and covenants to YNHH, including annual confirmation that neither Vendor nor any employee nor any independent third-party provider performing services under the Definitive Agreement has ever been (1) convicted of a criminal offense related to health care and/or related to the provision of services paid for by Medicare, Medicaid or another federal health care program; (2) excluded or debarred from participation in any federal health care program, including Medicare and Medicaid; or (3) otherwise sanctioned by the federal government, including being listed on the General Services Administration's Excluded Party Listing System.

(f) Vendor shall maintain appropriate insurance coverage, including commercial general liability, workers' compensation and commercial automobile liability, all by an insurer with an A.M. Best financial rating of "A-" or better.

(g) The Parties have entered into a Business Associate Agreement and shall comply with the terms thereof.

5. Confidentiality. Each Party agrees that this MOU is subject to the confidentiality obligations set forth in the existing agreement between the Parties dated January 12, 2018.

6. [Reserved]

7. [Reserved]

8. Term and Termination.

(a) This MOU shall commence on the date hereof and continue for eighteen (18) months or until terminated as provided herein.

(b) This MOU shall terminate automatically:

(i) upon the mutual agreement of the Parties; or

(iii) upon execution of the Definitive Agreement.

(c) This MOU may be terminated by either Party:

(i) if a default exists in the due observance of any of the covenants or agreements by any Party set forth herein; provided, however that such right of termination shall only apply if written notice of such default has been given and the defaulting party has not cured such default within thirty (30) days of receipt of such notice; or

(ii) if the conditions precedent for the Implementation Date referenced in Section 4 above have not been satisfied by December 31, 2020.

9. Public Communications. No public announcement regarding this MOU shall be made unless the Parties have mutually agreed in writing on the content and timing of such announcement. The Parties recognize, however, that the substance of this MOU will, in fact, be disclosed to the Office of Health Strategy as part of the Certificate of Need application in connection with the NHPCC.

10. Enforceability. This MOU reflects our mutual understanding of the matters described herein, but each party acknowledges that this MOU is not intended to create or constitute any legally binding obligation among the parties hereto with respect to the provision of transportation services unless and until a Definitive Agreement is prepared, authorized, executed and/or delivered by and between the parties. If a Definitive Agreement is not prepared, authorized, executed, and/or delivered for any reason, no party to this MOU shall have liability to any other party to this MOU based upon or relating to this MOU, other than obligations in connection with Sections 5, 6, 7, 8 and 9 hereof (Confidentiality, Term and Termination and Public Communications), which shall be binding.

11. Miscellaneous.

(a) This MOU shall be governed by the laws of the State of Delaware.

(b) This MOU shall not be amended or otherwise modified except by a written amendment duly executed by authorized representatives of both Parties.

(c) The failure of either Party hereto to insist upon strict adherence to any provision of this MOU on any occasion shall not be considered a waiver of such Party's right to insist upon strict adherence to such provision on any other occasion or to any other provision of this MOU in any instance. Any waiver shall be in writing signed by a duly authorized representative of the Party against whom such waiver is sought to be enforced.

(d) If one or more provisions of this MOU is found by an arbitrator or court of competent jurisdiction to be illegal, invalid or unenforceable in whole or in part, the remaining terms and provisions of this MOU shall remain in full force and effect disregarding such illegal, invalid or unenforceable portion and such arbitrator or court shall be empowered to modify, if possible, such unenforceable provision to the extent necessary to make this MOU enforceable in accordance with the intent and purposes of the Parties expressed herein to the fullest extent permitted by applicable law.

(e) The section headings contained in this MOU are for convenience only and they in no way define, limit or enlarge the scope of the provisions of such sections and shall not be considered in the interpretation or enforcement of this MOU.

(f) This MOU shall be deemed to have been drafted jointly by the Parties hereto and no presumption or rules of construction based upon the drafting of this MOU shall be made in any arbitration or legal proceedings arising hereunder.

IN WITNESS WHEREOF, the parties hereto have caused this MOU to be signed by their duly authorized officers as of the day and year first above written.

YALE-NEW HAVEN HOSPITAL, INC.

UBER HEALTH, LLC

By:  _____

By: Dan Trigub _____

Name: Michael F. Schaffer
Title: VP, Ambulatory Care
Date: May 28, 2019

Name: Dan Trigub
Title: Head of Uber Health
Date: May 28, 2019

EXHIBIT A

Service Standards

I. Driver standards:

- a) Vendor's independent third-party providers must agree to Vendor's requirements set forth in Vendor's Community Guidelines accessible at www.uber.com/legal/community-guidelines
- b) Maintain appropriate licenses
- c) Have passed all required background checks

Legal

UBER COMMUNITY GUIDELINES

We want Uber to be enjoyable and safe for everyone. These ground rules are designed to ensure that riders and drivers have a five star ride when using Uber. Please take a moment to read them. Because whether you're a rider trying to get from A to B — or a partner wanting to earn money as a driver — your behavior matters.

Respect each other

Treat your fellow riders and drivers as you would like to be treated yourself: with respect. Always try to be on time for your ride because nobody likes to wait. It's common courtesy not to shout, swear or slam the car door. And by tidying up after yourself — whether it's taking your trash home or cleaning up a spilled drink — you'll keep the car in good condition and ensure the next person has a pleasant ride, too. Most important of all, remember that when you use Uber you will meet people who may look different or think differently from you. Please respect those differences. We want everyone to feel welcome when they use Uber.

Give riders and drivers some personal space

We all value our personal space and privacy. It's OK to chat with other people in the car. But please don't comment on someone's appearance or ask whether they are single. As a passenger, if you need to make a phone call, keep your voice down to avoid disturbing your driver or other riders. And don't touch or flirt with other people in the car. As a reminder, Uber has a no sex rule. That's no sexual conduct between drivers and riders, no matter what.

Safety first

Everyone wants to get from A to B safely. So please ensure that you follow the local law. Check out our [rider safety tips](#). Whether you're in the front or the back seat, buckle up when you get into the car — and please leave your [guns at home](#). Of course, drivers have a particular responsibility when it comes to safety at Uber. That means keeping to the speed limit; not texting while driving; always using a phone mount; and never driving under the influence of alcohol or drugs. And if you're driving and feel tired, take a break. As the experts say, *"sleep is the only true preventative measure against the risks of drowsy driving."*

Children must be supervised

Only adults can have an Uber rider account. If your child is using your account, a parent or guardian must be with them at all times.

Feedback makes us all better

Whether you are a rider or driver, please rate your journey at the end of the trip. Honest feedback helps ensure that everyone is accountable for their behavior. This accountability creates a respectful, safe environment for both riders and drivers. And if something happens during a ride — whether it's a traffic accident or an argument — make sure to report it by tapping "Help" in the app so that our customer support team can follow up.

The guidelines below help explain some of the specific kinds of behavior that may cause you to lose access to Uber as a rider or driver.

WHY RIDERS CAN LOSE ACCESS TO UBER - US ONLY

This policy helps explain the kinds of behavior that may lead riders to lose access to Uber. Please remember that if you're traveling in a group, or you allow other people to take trips with your account, you are responsible for their behavior in the car.

Ensuring a respectful, safe environment for all drivers and riders

The way you behave while using Uber can have a big impact on the safety and comfort of drivers, as well as your fellow passengers. Courtesy matters. That's why you are expected to exercise good judgment and behave decently towards other people in the car when riding with Uber — just as you would in any public place.

Here are some reasons why you could lose access to Uber as a rider:

- **Damaging drivers' or other passengers' property.** For example, damaging the car, breaking or vandalizing a phone, intentionally spilling food or drink, smoking, or vomiting due to excessive alcohol consumption.
- **Physical contact with the driver or fellow riders.** As our community guidelines make clear, you shouldn't touch or flirt with other people in the car. As a reminder, Uber has a no sex rule. That's no sexual conduct with drivers or fellow riders, no matter what. And you should never hit or otherwise hurt a driver or fellow passenger.

- **Use of inappropriate and abusive language or gestures.** For example, asking overly personal questions, using verbal threats, and making comments or gestures that are aggressive, sexual, discriminatory, or disrespectful.
- **Unwanted contact with the driver or fellow passenger after the trip is over.** For example, texting, calling, or visiting someone in person after a ride has been completed. Remember, in most countries you can call and text your driver directly from the Uber app without having to share your personal phone number. This means that your phone number stays anonymous* and is not given to the driver.
**Anonymization features are not available in all markets and are subject to outage periods.*
- **Breaking the local law while using Uber.** For example, bringing open containers of alcohol or drugs into the car; traveling in large groups that exceed the number of seat belts in the car; asking drivers to break local traffic laws such as speed limits; or using Uber to commit a crime, including drug and human trafficking or the sexual exploitation of children.

If we are made aware of this type of problematic behavior, we may contact you so we can investigate them. Depending on the nature of the concern, we may put a hold on your account during our investigation. If the issues raised are serious or a repeat offense, or you refuse to cooperate, you may lose access to Uber. Any behavior involving violence, sexual misconduct, harassment, discrimination, or illegal activity while using Uber can result in the immediate loss of access to your account. Additionally, when law enforcement is involved, we will cooperate with their investigation in accordance with our [Law Enforcement Guidelines](#).

Terms of Use

As a rider, you agree to our [Terms of Use](#) when you sign up for your account. We may take action against you for violating these terms, including permanently closing your account. For example the failure to maintain accurate, complete, and up-to-date account information, including having an invalid or expired payment method on file; allowing a person who does not meet the minimum age requirement to use your account while unaccompanied, or if you don't meet that age requirement yourself.

Firearms Ban

Uber prohibits riders and drivers from carrying firearms in a vehicle while using our app. You can learn more about our firearms prohibition policy [here](#). [1] If you violate Uber's firearms prohibition policy, you may lose access to Uber.

Discrimination

Uber has a zero tolerance policy towards discrimination of any kind. This means you will lose access to your account if you are found to have discriminated against drivers or other riders based on their race, color, religion, national origin, disability, sexual orientation, sex, marital status, gender identity, age or any other characteristic protected under applicable law.

Fraud or Illegitimate Behavior

Fraudulent or illegitimate behavior undermines the trust on which Uber is built. We may deactivate any account(s) associated with this type of activity, including: abusing promotions; collusion between rider and driver; disputing fares for fraudulent or illegitimate reasons; or duplicate accounts.

WHY DRIVERS CAN LOSE ACCESS TO UBER - US ONLY

If you are a driver, and your account is temporarily blocked or deactivated, it limits your ability to earn income. That's why we believe it is important to have clear policies that explain the circumstances in which you may be denied access to Uber; how (if at all) you can use the app again; and if you can appeal these decisions. [2]

There will always be unforeseen events that may ultimately lead to you losing access to your driver account — and we'll update this policy regularly — but the following are sufficient cause for Uber to take action: quality; safety; fraud; and discrimination.

Quality

Riders who use Uber expect their drivers to drive safely, and also to be courteous and professional. The higher the quality of the service, the more riders want to take trips, which in turn means more opportunities for drivers to earn money. Poor service has the opposite effect over time. There are several ways we measure driver quality, with the most important being Star Ratings and Cancellation Rate.

Star Ratings

After every trip, drivers and riders are able to rate each other on a scale of one to five stars, as well as give feedback on how the trip went. This two-way system holds everyone accountable for their behavior. Accountability helps create a respectful, safe environment for both drivers and riders.

Drivers can see their current rating in the Ratings tab of the Uber Partner app.

How is my rating as a driver calculated? Your rating is based on an average of the number of post-trip stars riders gave you (from 1 to 5 stars), up to your last 500 rated trips or the total number of rated trips you've taken, if less than 500.

The easiest way to keep your average rating high is to provide good service on every trip. Drivers using Uber typically provide excellent service, so most trips run smoothly. But we know that sometimes a trip doesn't go well—that's why we only look at your average rating over your most recent 500 trips (or your total rated trip count, if under 500). This gives you the chance to improve over time.

What leads to you losing access to your account? There is a minimum average rating in each city. This is because there are cultural differences in the way people in different cities rate each other. We will alert you over time if your rating is approaching this limit, and you'll also get information about quality improvement courses that may help you improve. However, if your average rating still falls below the minimum after multiple notifications, you will lose access to your account. We may allow you to regain access to your account if you can provide proof that you completed one of these quality improvement courses.

Cancellation Rate

A driver cancellation is when you accept a trip request and then cancel the trip. Cancellations create a poor rider experience and negatively affect other drivers. We understand that there may be times when something comes up and you have to cancel an accepted trip. But minimizing cancellations is critical for the reliability of the system.

How is my cancellation rate calculated? Your cancellation rate is based on the number of trips canceled out of the total number of trips you accept. (For example, if you've accepted 100 trips and 4 of them are canceled, your cancellation rate would be 4%.) High-quality drivers typically have a cancellation rate lower than 5%.

What leads to you losing access to your account? Each city has a maximum cancellation rate, based on the average cancellation rate of drivers in that area. We will alert you multiple times if your cancellation rate is much higher or if you are consistently canceling more often than other drivers in your city, after which you may be logged out of the app. If your cancellation rate continues to exceed the maximum limit, you may lose access to your account.

Acceptance Rates

High acceptance rates are a critical part of reliable, high-quality service, but not accepting trip requests does not lead to permanent loss of your account.

Consistently accepting trip requests helps maximize earnings for drivers and keeps the system running smoothly. We know that sometimes things come up that prevent you from accepting every trip request, or you may want to take a break. But not accepting trip requests causes delays and degrades the reliability of the system. If you don't want to accept trips, just log off.

If you consistently decline trip requests, we will assume you do not want to accept more trips and you may be logged out of the app. [3]

Safety

Uber uses technology to keep drivers and riders safe, for instance by GPS-tracking every ride and allowing riders to share their journeys in real time with families or friends. This is all backed up by a robust system of pre-screenings of drivers. We also have a dedicated incident response team on call 24/7 to investigate safety incidents.

Actions that threaten the safety of drivers and riders will be investigated and, if confirmed, lead to permanent deactivation of your account. For example:

- **Physical contact with riders.** As our community guidelines make clear, you shouldn't touch or flirt with other people in the car. As a reminder, Uber has a no sex rule. That's no sexual conduct with riders, no matter what. And you should never hit or otherwise hurt a rider.
- **Use of inappropriate and abusive language or gestures.** For example, asking overly personal questions, using verbal threats, and making comments or gestures that are aggressive, sexual, discriminatory, or disrespectful.
- **Unwanted contact with riders after a trip is over.** For example, texting, calling, or visiting someone in person after a ride has been completed.
- **Breaking the local law while using Uber.** For example, texting while driving; speeding or otherwise breaking local traffic laws; and using Uber to commit a crime, including drug and human trafficking or the sexual exploitation of children.
- **Safe Driving.** Uber expects drivers using the app to drive safely at all times.

What leads to you losing access to your account? If we are made aware of this type of problematic behavior, we may contact you so we can investigate them. Depending on the nature of the concern, we may put a hold on your account during our investigation. If the issues raised are serious or a repeat offense, or you refuse to cooperate, you may lose access to Uber. Any behavior involving violence, sexual misconduct, harassment, discrimination, or illegal activity while using Uber can result in the immediate loss of your account. Uber will also deactivate the account of any driver who receives several or serious complaints of poor, unsafe, or distracted driving while using the Uber app. Additionally, when law enforcement is involved, we will cooperate with their investigation in accordance with our [Law Enforcement Guidelines](#).

Zero Tolerance for Drugs and Alcohol

Uber does not tolerate the use of drugs or alcohol by partners while driving.

What leads to you losing access to your account? The account of any driver found to be under the influence of drugs or alcohol while using the Uber app will be permanently deactivated. Uber may also deactivate the account of any driver who receives several unconfirmed complaints of drug or alcohol use.

Compliance with the Law

We expect drivers using the Uber app to act in compliance with all relevant state, federal and local laws and the rules of the road at all times. This includes meeting the regulatory requirements for rideshare or for-hire drivers in your area.

What leads to you losing access to your account? Uber may permanently deactivate your account for activities such as: engaging in serious illegal activity while using the Uber app; not maintaining valid vehicle registration or driver's license; and receiving serious traffic citations, or several traffic citations that indicate unsafe driving, while using the Uber app.

Firearms Ban

Uber prohibits riders and drivers from carrying firearms in a vehicle while using our app. You can learn more about our firearms prohibition policy [here](#). [1] If you violate Uber's firearms prohibition policy, you may lose access to Uber.

Background Checks

All drivers wanting to use the Uber app are required to undergo a screening process, like motor vehicle record and background checks, to ensure safety and compliance with our criteria. [4]

What leads to you losing access to your account? We will permanently deactivate a driver's account if a routine motor vehicle record or background check uncovers a violation of Uber's safety standards or of other criteria required by local regulators.

Unacceptable Activities

To maintain the transparency and safety of each trip for all users, activities conducted outside of Uber's system — like anonymous pickups — are prohibited.

What leads to you losing access to your account? We will take action against a driver for activities such as: accepting illegal street hails while using the Uber app; harming the business or brand, like unauthorized use of Uber's trademark or intellectual property, or otherwise violating the drivers' agreement with Uber; and soliciting payment of fares outside the Uber system.

Fraud

Fraudulent activity undermines the trust on which Uber is built. That's why we are constantly on the lookout for fraud by riders and drivers who are gaming our systems.

What leads to you losing access to your account? We will deactivate any account or accounts associated with fraudulent activity, which may include: deliberately increasing the time or distance of a trip; accepting trips without the intention to complete, including provoking riders to cancel; creating dummy rider or driver accounts for fraudulent purposes; claiming fraudulent fees or charges, like false cleaning fees; and intentionally accepting or completing fraudulent or falsified trips.

Accurate Personal Information

The Uber app is designed to give riders identifying information about drivers and their vehicles, like their name, profile picture, vehicle model and license plate number, before the trip begins. Inaccurate or outdated information creates confusion among riders and can diminish their experience with Uber.

What leads to you losing access to your account? We will deactivate your account for activities such as: providing Uber with inaccurate information; allowing someone else to use your account; and taking a trip using an unapproved vehicle.

In addition, we will take action to prevent any driver whose required documentation becomes invalid — like a driver’s license that expires — from going online until the driver provides Uber with updated information.

Discrimination

Uber’s mission is to connect riders to reliable transportation, everywhere for everyone. We have a zero tolerance policy towards discrimination of any kind at Uber.

What leads to you losing access to your account? It is unacceptable to refuse to provide services based on characteristics like a person’s race, color, religion, national origin, disability, sexual orientation, sex, marital status, gender identity, age or any other characteristic protected under relevant federal, state, or local law. Actions like these may result in permanent deactivation of your account.

In addition, it is not acceptable to discriminate on the basis of a rider’s destination.

What does this mean? We understand how important it is to fit driving around your life, rather than the other way around. It is not a violation of these guidelines to pass on a trip because the trip does not work for you—for example, it would interfere with a personal commitment or prior obligation, such as a job, a doctor’s appointment, a school pick-up, or a family event. But cancelling trips or using features in the Uber app to avoid receiving trip requests solely for the purpose of avoiding a particular neighborhood due to the characteristics of the people or businesses that are located there violates these guidelines and may cause you to lose access to your account.

We also want to help increase the transportation options for riders with disabilities. That’s why we have information available for drivers on this topic. See [here](#) for more on Uber’s commitment to accessibility. We expect drivers using the Uber app to comply with all relevant state, federal and local laws governing the transportation of riders with disabilities, including transporting service animals.

Getting Back on the Road After Deactivation

If your account has been deactivated for quality reasons like low star ratings, you may have the opportunity to get back on the road if you provide proof that you’ve successfully taken a quality improvement course offered by third party experts, available in most U.S. cities today. Check with your local Uber team or help.uber.com to find out more. We are also exploring whether these experts provide the option of an equivalent online course, so that this is available to drivers everywhere in the United States at a low cost. In addition, we are exploring ways to create an appeals process for the most contentious cases. We will update this document as and when we have that process in place.

We're here to help

Support is just a few taps away. You can also get your questions answered by using our help section.

[Get help](#)

[↵](#)

[Uber](#)

English

Connecticut

Seeing information for this city

Inserted from <https://www.uber.com/legal/community-guidelines/us-en/>

Exhibit 4

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON

STATE OF OREGON et al.,

Plaintiffs,

v.

ALEX M. AZAR II et al.

Defendants,

and

AMERICAN MEDICAL ASSOCIATION,
et al.,

Plaintiffs,

v.

ALEX M. AZAR II et al.,

Defendants.

MCSHANE, Judge:

Plaintiffs in these consolidated actions are 20 states, the District of Columbia, the American Medical Association, the Oregon Medical Association, the Planned Parenthood Federation and their local affiliates, and individual medical providers. They seek to enjoin the

6:19-cv-00317-MC (Lead Case)
6:19-cv-00318-MC (Trailing Case)

OPINION AND ORDER

United States Department of Health and Human Services, the Office of Population Affairs, and their respective leadership (collectively, the “Defendants” or “HHS”) from implementing certain rules (the “Final Rule”) that would alter the family planning program established by Title X of the Public Health Service Act, 42 U.S.C. § 300 *et seq.* The Final Rule was issued by HHS on March 4, 2019, and its effective date is May 3, 2019.

At the heart of their claims, Plaintiffs allege that the Final Rule is antithetical to public health and is a fundamental shift in policy away from Title X’s emphasis on nondirective and voluntary family planning between low-income patients and their medical providers. Indeed, the rule would, among other things, dramatically limit medical professionals from discussing abortion options with their patients and completely prohibit them from referring patients seeking an abortion to a qualified provider (the “Gag Rule”). It would also require Title X providers to physically and financially divorce health services funded under Title X from abortion services funded from sources other than Title X (the “Separation Requirement”).

At best, the Final Rule is a solution in search of a problem. At worst, it is a ham-fisted approach to health policy that recklessly disregards the health outcomes of women, families, and communities. In the guise of “program integrity,” the Gag Rule prevents doctors from behaving like informed professionals. It prevents counselors from providing comprehensive counseling. It prevents low-income women from making an informed and independent medical decision. At the heart of this rule is the arrogant assumption that government is better suited to direct the health care of women than their medical providers. At a time in our history where government is assessing how we can improve and lower the costs of medical care to all Americans, the Final Rule would create a class of women who are barred from receiving care consistent with accepted and established professional medical standards. On top of that, the Separation Requirement

would create such a financial strain on Title X providers that, ironically, it would create a geographic vacuum in family planning that experts warn would lead to substantially more unintended pregnancies and, correspondingly, more abortions.

The harms outlined in the record before me, should the Final Rule be implemented, are extensive and are not rebutted by the government. A review of the scores of declarations from public health policy experts, medical organizations, doctors, and Title X providers lead to the inescapable conclusion that the Final Rule will result in negative health outcomes for low income women and communities. It will result in less contraceptive services, more unintended pregnancies, less early breast cancer detection, less screening for cervical cancer, less HIV screening, and less testing for sexually transmitted disease. HHS's response to these negative health outcomes is one of silence and indifference. Rather than providing contradictory data to support any positive health outcomes, they rationalize that the Final Rule "will ensure compliance with, and implementation of, the statutory requirement that none of the funds appropriated for Title X may be used in programs where abortion is a method of family planning." At the same time, despite the nearly fifty-year history of Title X, they cannot point to one instance where Title X funds have been misapplied under past or current rules.

Without revealing what evidence, if any, helped shape its opinions, HHS essentially says, "trust us, this will work out fine." But dramatic changes to the only federal program providing family planning services to millions of clients in marginalized communities requires something more than a mere hunch. The dearth of evidence and lack of transparency in HHS's rulemaking is particularly concerning as HHS earlier concluded that there was "no evidence that [the Gag Rule] can and will work operationally on a national basis in the Title X program." 65 Fed. Reg. at 41,271.

Should the Final Rule go into effect in mere days, the risk of irreparable damage to the health of women and communities is grave. In contrast, keeping the current regulations in place—regulations that “have been used by the program for virtually its entire history,” *id.*, and have provided critical medical services for at-risk communities—poses no harm to Defendants.

As discussed below, Plaintiffs are likely to succeed on the merits of their claim that the Final Rule is contrary to law. Additionally, Plaintiffs raise serious questions going to the merits of their claims that the Final Rule is arbitrary and capricious. Plaintiffs have demonstrated the likelihood of “irreparable harm” and that the balance of equities tips sharply in their favor. Plaintiffs’ Motions for a Preliminary Injunction are GRANTED.

FACTUAL BACKGROUND

Congress enacted the Title X program, known as the “Population Research and Voluntary Planning Program,” in 1970 as part of the Public Health Services Act. Its mission is to provide grants to public and non-profit organizations “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).” 42 U.S.C. § 300(a). Title X targets low income families and individuals and provides family planning services at low or no cost. The stated purpose of Title X is to promote positive birth outcomes and healthy families by allowing individuals to decide the number and the spacing of their children.

Congress authorized HHS to promulgate regulations to effectuate Title X’s mission, largely through the award of grants to providers of family planning services to low income individuals. 42 U.S.C. § 300a-4. Title X grants are administered by the Office of the Assistant Secretary for Health through the Office of Population Affairs. The statute and regulations of

Title X require that 90 percent of congressional appropriations be used for clinical family planning purposes. Title X funds a broad array of family planning services: contraceptive services, information, and education; natural family planning and education; infertility services; services to adolescents; HIV and sexually transmitted disease screening and referral; breast and cervical cancer screenings; and pregnancy testing.

By all accounts, for nearly 50 years, the Title X program has been a great success in meeting its stated goals. According to HHS's 2017 Summary, the program served over 4 million family planning clients at 3,858 service sites through 6.6 million family planning encounters. Those served are largely from vulnerable populations who would not otherwise have access to health care. Title X clinics provided over 2 million Chlamydia tests, 2.5 million Gonorrhea tests, 2 million HIV tests, and over 700,000 syphilis tests. Title X providers conducted Pap screening on nearly 650,000 clients and breast exams on 878,492 women. *See* Title X Family Planning Annual Report 2017 Summary, www.hhs.gov/opa/title-x-family-planning/fp-annual-report/fpar-2017 (last visited April 25, 2019). By regularly providing millions of patients with contraceptive services, the Title X program has significantly reduced the rates of unintended pregnancy and abortion. In fact, unintended pregnancies and abortions are now at historic lows, in large part due to Title X. Kost Decl. ¶¶ 7, 35, ECF No. 53; Brindis Decl. ¶ 26, ECF No. 52; Lawrence B. Finer & Mia R. Zolna, *Declines in Unintended Pregnancy in the United States, 2008-2011*, 374 *New Eng. J. Med.* 843, 850 (2016) (noting unintended pregnancy rate in United States dropped to a 30-year low in 2011).

At issue in this case is the agency's interpretation of the congressional mandate found in the final sentence of Title X known as "Section 1008." 42 U.S.C. § 300a-6. This mandate requires that "None of the funds appropriated under this title shall be used in programs where

abortion is a method of family planning.” 42 U.S.C. § 300a-6. Historically, HHS has taken the position that medical professionals may provide neutral and factual information, even concerning abortion, as a part of pregnancy counseling. The agency squared such counseling with Section 1008 because “the provision of neutral and factual information about abortion is not considered to promote or encourage abortion as a method of family planning.” 65 Fed. Reg. at 41,271. HHS generally allowed the medical professional’s objective professional judgment, aided by the patient’s particular needs, to drive pregnancy counseling. Earlier rules also allowed abortion referrals.

The Final Rule deviates sharply from the historical interpretation of Section 1008. HHS used the same justification—that the Final Rule will ensure compliance with Section 1008’s requirement that no Title X funds “shall be used in programs where abortion is a method of family planning”—in 1988 when it promulgated similar rules. Those rules, like the Final Rule at issue here, prohibited abortion referrals and required strict financial and physical separation between Title X projects and services prohibited by Title X.

Numerous Title X grantees and doctors impacted by the 1988 rule challenged the regulations alleging, as relevant here, that the Gag Rule and Separation Requirement were not authorized by Title X and thus were arbitrary and capricious. The Supreme Court ultimately upheld the 1988 rules. The Court examined Section 1008’s prohibition on using Title X funds “in programs where abortion is a method of family planning.” The Court, like every other court to examine the statutory language and legislative history of Section 1008, found the statute ambiguous. “If a statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency’s answer is based on a permissible construction of the statute. The Secretary’s construction of Title X may not be disturbed as an abuse of discretion if it

reflects a plausible construction of the plain language of the statute and does not otherwise conflict with Congress' expressed intent." *Rust, v. Sullivan*, 500 U.S. 173, 184 (1991) (internal quotations and citation omitted). The fact that the 1988 rules represented a "sharp break with prior interpretations" by HHS did not mean the new rules were invalid, because "the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis." *Id.* at 185 (quoting *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 862 (1984)). In rejecting Plaintiffs' arguments challenging the Gag Rule, Justice Rehnquist concluded HHS adequately justified the change from prior policy:

The Secretary explained that the regulations are a result of his determination, in the wake of the critical reports of the General Accounting Office (GAO) and the Office of the Inspector General (OIG), that prior policy failed to implement properly the statute and that it was necessary to provide 'clear and operational guidance' to grantees about how to preserve the distinction between Title X programs and abortion as a method of family planning.' 53 Fed. Reg. 2923-2924 (1988). He also determined that the new regulations are more in keeping with the original intent of the statute, are justified by client experience under the prior policy, and are supported by a shift in attitude against the 'elimination of unborn children by abortion.' We believe that these justifications are sufficient to support the Secretary's revised approach. Having concluded that the plain language and legislative history are ambiguous as to Congress' intent in enacting Title X, we must defer to the Secretary's permissible construction of the statute.

Id. at 173.

As for the Separation Requirement, the Court found that "the program integrity requirements are based on a permissible construction of the statute and are not inconsistent with congressional intent." *Id.* at 188. Once again, the Secretary adequately justified his reasoning:

Indeed, if one thing is clear from the legislative history, it is that Congress intended that Title X funds be kept separate and distinct from abortion-related activities. It is undisputed that Title X was intended to provide primarily pre-pregnancy preventative services. Certainly the Secretary's interpretation of the statute that separate facilities are necessary, especially in light of the express prohibition of § 1008, cannot be judged unreasonable. Accordingly, we defer to

the Secretary's reasoned determination that the program integrity requirements are necessary to implement the prohibition.

Id. at 190.

Although the Court allowed the 1988 rules to stand, HHS never implemented those regulations on a national scale. 65 Fed. Reg. at 41,271. And, in 1993, HHS suspended the 1988 regulations, finding them to be "an inappropriate implementation of the Title X statute." 58 Fed. Reg. at 7464.

In 1996 (five years after the Supreme Court's decision in *Rust*), Congress clarified that its prohibition on Title X abortion funding did not prohibit the nondirective counseling of pregnant women. To the contrary, Congress mandated that "all pregnancy counseling shall be nondirective" with respect to Title X. Omnibus Consolidated Rescissions and Appropriations Act, 1996, Pub. L. No. 104-134, Title II, 110 Stat. 1321 (1996). This congressional mandate has appeared in every subsequent Title X appropriations statute from 1996 until present. *See* Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. Law. No 115-245, Title II, 132 Stat. 2981, 3070-71 (September 28, 2018).

In 2000, HHS issued new Title X rules that remain in effect to this day. The 2000 regulations officially revoked the 1988 rules that were validated by the *Rust* court but never implemented by HHS. The agency concluded that the Gag Rule from the 1988 rules "endangers women's lives and health by preventing them from receiving complete and accurate medical information and interferes with the doctor-patient relationship by prohibiting information that medical professionals are otherwise ethically and legally required to provide to their patients." 65 Fed. Reg. at 41,270. The 2000 rules required the provider to offer the pregnant woman the

opportunity to be “provided information and counseling regarding each of the following options: (A) Prenatal care and delivery; (B) Infant care, foster care, or adoption; and (C) Pregnancy termination. 65 Fed. Reg. at 41,279. Regarding nondirective counseling, the 2000 rules provided:

If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.

Id.

Nondirective counseling meant the grantee “may not steer or direct clients toward selecting any option, including abortion[.]” *Id.* at 41,273. Referrals for abortion were once again allowed, provided the client requested such a referral. *Id.* at 41,274. Finally, HHS determined that financial separation, rather than financial and physical separation, was sufficient to abide by Section 1008.

Ten years after HHS implemented the 2000 regulations still in place today, Congress spoke again on the matter. In passing the Affordable Care Act in 2010, Congress once again limited the rulemaking authority of HHS. There, Congress expressly prohibited HHS from promulgating any regulation that:

(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient’s medical needs.

42 U.S.C. § 18114.

Given the above context, I turn to the Final Rule at issue here. HHS published the Final Rule in the Federal Register on June 1, 2018. During the 60-day public comment period, HHS

received more than 500,000 comments. Certain revisions were made to the proposed rule and HHS published the Final Rule in the Federal Register on March 4, 2019.¹ The rule has an implementation date of May 3, 2019.

As expressed by HHS in its executive summary, the purpose of the Final Rule, as it relates to Section 1008, is “to ensure compliance with, and enhance implementation of, the statutory requirement that none of the funds appropriated for Title X may be used in programs where abortion is a method of family planning.” 84 Fed. Reg. at 7717. For purposes of this litigation, Plaintiffs’ claims center on two aspects of the final rule that they refer respectively to as: (1) The Gag Rule; and (2) The Separation Requirement.

Turning first to the Gag Rule, the Final Rule provides that a “Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion.” 84 Fed. Reg. at 7788-89 (to be codified at 42 C.F.R. § 59.14). Without doubt, the Final Rule limits the provider’s options when presented with a pregnant woman.

First, once a patient is identified as pregnant, “she shall be referred to a health care provider for medically necessary prenatal health care.” 84 Fed. Reg. at 7789 (to be codified at 42 C.F.R. § 59.14). This referral for prenatal health care is mandatory. Next, the provider may, but is not required to, “provide the following counseling and/or information to her:”

- (i) Nondirective pregnancy counseling, when provided by physicians or advanced practice providers;
- (ii) A list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care);
- (iii) Referral to social services or adoption agencies; and/or

¹ Plaintiffs filed their complaints the following day, on March 5, 2019. Due to the closely-approaching implementation date, the court set an expedited briefing schedule and, just days ago, heard oral arguments.

- (iv) Information about maintaining the health of the mother and unborn child during pregnancy.

Id.

If the provider chooses to provide a list of comprehensive health care providers, the list “may be limited to those that do not provide abortion, or may include licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), some, but not the majority, of which also provide abortion as part of their comprehensive health care services. Neither the list nor project staff may identify which providers on the list perform abortions.” *Id.*

Plaintiffs also challenge the Final Rule’s Separation Requirement. The Separation Requirement provides that any “Title X project must be organized so that it is physically and financially separate . . . from activities which are prohibited [in the Final Rule].” 84 Fed. Reg. at 7789 (to be codified at 42 C.F.R. § 59.15). According to HHS, complete physical and financial separation between a Title X program and any activities falling outside of Title X is necessary to: (1) comply with Section 1008; (2) eliminate the “significant risk for public confusion” over whether Title X funds are allocated for abortion-related purposes; and (3) “address the concern that Title X resources could facilitate the development of, and ongoing use of, infrastructure for non-Title X activities.” 84 Fed. Reg. at 7715.

Plaintiffs ask the court to issue a nationwide preliminary injunction restraining HHS from implementing the Final Rule. Absent an injunction, the Final Rule goes into effect in four days, on May 3, 2019.

STANDARDS

A plaintiff seeking a preliminary injunction must establish: (1) likelihood of success on the merits; (2) irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in his favor; and (4) an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). When, as here, the government is a party, the last two factors merge. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). When there are “serious questions going to the merits,” a court may still issue a preliminary injunction when “the balance of hardships tips sharply in the plaintiff’s favor,” and the other two factors are met. *All. for the Wild Rockies v. Pena*, 865 F.3d 1211, 1217 (9th Cir. 2017) (quoting *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011)). The court’s decision on a motion for a preliminary injunction is not a ruling on the merits. *See Sierra On-Line, Inc. v. Phoenix Software, Inc.*, 739 F.2d 1415, 1422 (9th Cir. 1984).

DISCUSSION

Under the APA, a court’s review of an agency decision should be searching but narrow, and the reviewing court should take care not to substitute its judgment for that of the agency. *Oregon Wild v. United States*, 107 F. Supp. 3d 1102, 1109 (D. Or. 2015) (citing *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971)). Under this review, the court “shall hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706.

As noted, many of the arguments put forward by Plaintiffs are ones the Supreme Court previously rejected when considering the (remarkably similar) rules in *Rust*. At first blush, one could be persuaded that *Rust* controls the outcome here. In fact, most of HHS’s arguments—specifically in its written response, where it cited *Rust* on 168 occasions—simply point to *Rust* as

evidence the Final Rule is a lawful exercise of agency discretion. *See Defs. ' Opp'n*, 17; ECF No. 83 (“*Rust’s* on-point statutory holding—and the remarkable overlap between Plaintiffs’ arguments and the ones *Rust* rejected—disposes of the claim that the materially indistinguishable Rule is unlawful.”).

HHS would seemingly have the court believe *Rust* concluded the Gag Rule and Separation Requirement were required interpretations of Section 1008. But *Rust* contains no such holding. *Rust* merely held that in light of the ambiguous nature behind Congress’s intent in enacting Title X generally, and Section 1008 specifically, HHS’s interpretation of Section 1008 was not unreasonable:

The broad language of Title X plainly allows the Secretary’s construction of the statute. By its own terms, § 1008 prohibits the use of Title X funds “in programs where abortion is a method of family planning.” Title X does not define the term “method of family planning,” nor does it enumerate what types of medical and counseling services are entitled to Title X funding. Based on the broad directives provided by Congress in Title X in general and § 108 in particular, we are unable to say that the Secretary’s construction of the prohibition in § 1008 to require a ban on counseling, referral, and advocacy within the Title X project is impermissible.

Rust, 500 U.S. at 184.

Additionally, the Court clarified that “[a]t no time did Congress directly address the issues of abortion counseling, referral, or advocacy.” *Id.* at 185. Given the lack of direction from Congress, and considering HHS provided ample justification for its reasoning in revising the rules, the Court deferred to the agency’s “permissible construction of the statute.” *Id.* at 187.

Two significant facts, however, separate this case from *Rust*. First, Congress has consistently mandated since 1996 that “that all pregnancy counseling shall be nondirective” with respect to Title X. Omnibus Consolidated Rescissions and Appropriations Act, 1996 Pub. L. No. 104-134, Title II, 110 Stat. 1321, 1321-22 (1996). Second, the 2010 limitations Congress

included in the Affordable Care Act significantly limit HHS's rulemaking authority. Therefore, HHS must do more than merely dust off the 30-year old regulations and point to *Rust*.

HHS makes the head-scratching argument that neither of the post-*Rust* laws enacted by Congress can serve as an implied repeal of Section 1008 or overrule *Rust*. HHS argues, "A clear, authoritative judicial holding on the meaning of a particular provision should not be cast in doubt and subjected to challenge whenever a related though not utterly inconsistent provision is adopted in the same statute or even in an affiliated statute." *Defs. ' Opp'n*, 19 (quoting *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1520 (2017)). That premise is certainly correct. But *TC Heartland* involved a statutory term the Supreme Court previously had "definitively and unambiguously held . . . has a particular meaning[.]" 137 S. Ct. at 1520. The Court therefore quite appropriately pointed out that "[T]he modification by implication of the settled construction of an earlier and different section is not favored." *Id.* (quoting *United States v. Madigan*, 300 U.S. 500, 506 (1937)). But the rule regarding implied repeal has no application here, where *Rust* expressly held that the statute in question was ambiguous. Again, *Rust* merely held that because Congress had not spoken on the matter, HHS's Gag Rule and Separation Requirement were reasonable interpretations of Section 1008 at that time. But Congress has since spoken on the matter.

Additionally, I note that absolutely nothing in the appropriations mandate that "all pregnancy counseling shall be nondirective," or the express limitations Congress placed on HHS's rulemaking authority in the ACA, necessarily conflict with Section 1008's requirement that "[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning." HHS's vigor in arguing that the appropriations act and the ACA "cannot repeal Section 1008" or "overrule *Rust*" only demonstrates that the Final Rule

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conflicts with both statutes. After all, not all interpretations place the three statutes at odds with one another. The current regulations, which have been in place for nearly five decades, allow Section 1008, the appropriations language, and the ACA restrictions to live in harmony. *Rust* explicitly commented that the plaintiffs' argument that the legislative history behind Title X rendered the 1988 rules contrary to law was, in fact, one permissible interpretation. *Rust*, 500 U.S. at 189. But because HHS's interpretation was also a permissible interpretation, deference to the agency's reasonable interpretation carried the day. *Id.* ("While petitioner's interpretation of the legislative history may be a permissible one, it is by no means the only one, and it is certainly not the one found by the Secretary."). The question now is whether, given the two new statutes, HHS's 30-year-old rules remain "one permissible interpretation."

I turn first to the Final Rule's Gag Rule. As noted, the Final Rule prohibits referrals for abortions. HHS argues that although "all pregnancy counseling shall be nondirective," Congress said nothing about referrals. This argument appears a stretch. First, HHS includes referrals within pregnancy counseling in the Final Rule. For example, in its guidance for nondirective pregnancy counseling, the agency states, "Title X projects should not use nondirective pregnancy counseling, or referrals made for prenatal care or adoption during such counseling, as an indirect means of encouraging or promoting abortion as a method of family planning." 84 Fed. Reg. at 7747 (emphasis added). The above guidance aligns with Congress's thoughts on referrals. Congress, in ordering HHS to make grants available to assist "*in providing* adoption information and referrals to pregnant women on an equal basis *with all other courses of action included in nondirective counseling* to pregnant women," clearly included referrals in nondirective counseling. 42 U.S.C. § 254c-6(a)(1) (emphasis added).

Although common sense, the agency's own guidance, and Congress's statutory language indicate pregnancy counseling includes referrals, a different outcome would not save the Final Rule from violating the requirement that all pregnancy counseling be nondirective. Regardless of the referral process (discussed further below), the Final Rule blatantly requires that any pregnancy counseling for abortion be directive. For the Final Rule, this is a problem, as it is well established that Congress "may amend substantive law in an appropriations statute, as long as it does so clearly." *Robertson v. Seattle Audobon Soc'y*, 503 U.S. 429, 441 (1992). Congress is quite clear on its thoughts regarding pregnancy counseling: "all pregnancy counseling shall be nondirective."

Although the Final Rule does not define "nondirective counseling," it provides guidance on the term. The agency describes "nondirective counseling" as:

the meaningful presentation of options where the physician or advanced practice provider (APP) is not suggesting or advising one option over another. . . . Nondirective counseling does not mean that the counselor is uninvolved in the process or that counseling and education offer no guidance, but instead that clients take an active role in processing their experiences and identifying the direction of the interaction. In nondirective counseling, the Title X physicians and APPs promote the client's self-awareness and empower the client to be informed about a range of options, consistent with the client's expressed need and with the statutory and regulatory requirements governing the Title X program. *In addition, the Title X provider may provide a list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), some (but not the majority) of which may provide abortion in addition to comprehensive primary care.*"²

84 Fed. Reg. at 7716 (internal quotations, citation, and footnote omitted) (emphasis added).

Examining the Final Rule's requirement for abortion counseling confirms it is anything but nondirective. After confirming that the provider need not provide any pregnancy counseling

² The emphasized portion, concerning a type of referral, which appears in the Final Rule's section on guidance for what "Nondirective pregnancy counseling is," is yet another example that the agency (along with all of the expert opinions submitted in the record) views referrals as simply one portion of the entire counseling process.

at all, the Final Rule outlines what counseling is permissible should the provider decide to offer such counseling:

Nondirective counseling is designed to assist the patient in making a free and informed decision. *In nondirective counseling, abortion must not be the only option presented by physicians or APPs*; otherwise the counseling would violate the Congressional directive that all pregnancy counseling be nondirective, but also the prohibitions in this rule on encouraging, advocating, or supporting abortion as a method of family planning, which the Department prohibits in order to implement, among other provisions, section 1008. Each option discussed in such counseling must be presented in a nondirective manner. This involves presenting the options in a factual, objective, and unbiased manner and (consistent with the other Title X requirements and restrictions) offering factual resources that are objective, rather than presenting the options in a subjective or coercive manner. *Physicians or APPs should discuss the possible risks and side effects to both mother and unborn child of any pregnancy option presented*, consistent with the obligation of health care providers to provide patients with accurate information to inform their health care decisions.

84 Fed. Reg. at 7747 (emphasis added).

Like nearly every other aspect of the Final Rule, the agency creates one set of rules for abortion, and a separate set of rules for everything else. Back in 1988, this was a permissible interpretation of the then lone congressional requirement that no Title X funds “be used in programs where abortion is a method of family planning.” But when implementing a rule in 2019, HHS must comply not only with Section 1008, but also with Congress’s requirement that “all pregnancy counseling be nondirective.” HHS’s mistake, here and throughout the Final Rule, assumes that Section 1008 trumps Congress’s other mandates. But as noted above, the statutes are not irreconcilable.

For all pregnancy counseling not involving abortion, the Final Rule allows “the clients [to] take an active role in processing their experiences and identifying the direction of the interaction . . . [while allowing the providers to] promote the client’s self-awareness and empower the client to be informed about a range of options, *consistent with the client’s*

expressed need[.]” 84 Fed. Reg. at 7716 (emphasis added). This is not the case, however, if the empowered client wishes to exercise abortion in that range of options. During abortion counseling, the medical professional no longer provides neutral, factual information “consistent with the client’s expressed need[.]” Fed. Reg. at 7716. Instead, the provider must provide counseling regarding some other option the client has no use for, even when it is not requested by the client or even medically relevant.³ The Gag Rule is the very definition of directive counseling. It makes no difference that HHS labels this process “nondirective counseling,” or that HHS states such requirements are necessary to avoid, according to HHS’s own interpretation, “the prohibitions in this rule on encouraging, advocating, or supporting abortion as a method of family planning [under Section 1008].” 84 Fed. Reg. at 7747. It is clear that while giving lip service to the requirement that all pregnancy counseling be nondirective, HHS never sought to actually interpret that mandate in coordination with Section 1008. As the Gag Rule is not “in accordance with the law,” it violates the APA. 5 U.S.C. § 706(2)(A).

As odd as the pregnancy counseling process is, it pales in comparison to the Final Rule’s requirements for abortion referrals. One would expect to find such a process not in a federal program serving millions of clients, but in a Kafka novel. As described above, if a woman seeks to have a legal abortion and requests a referral from her Title X provider, the Final Rule requires a referral for prenatal care. That is, the provider is mandated to refuse to provide the referral the client wants, and instead provide a referral the client neither needs nor requested. *See* 84 Fed. Reg. 7789 (to be codified at 42. C.F.R. § 59.14(b)) (requiring that after the client is “verified as

³ For some reason—and the Court struggles here with finding any rational relationship to any medical purpose—the Final Rule allows, and in fact encourages, that the provider “should discuss the possible risks and side effects to both mother and unborn child of any pregnancy option presented[.]” 84 Fed. Reg. at 7747. In other words, the Final Rule encourages the provider to counsel a woman who has chosen to proceed with a legal abortion on the possible risks and side effects to the fetus.

pregnant, she shall be referred to a health care provider for medically necessary prenatal health care”).

Amazingly, the Final Rule allows the provider, at its whim, to refer the woman not to an abortion clinic, but to an adoption agency. *Id.* § 59.14(b)(1)(iii).⁴ Or, the provider may provide a list of primary care providers, none of whom actually perform abortions. *Id.* § 59.14(c)(2). The rule also allows the counselor to provide “[i]nformation about maintaining the health of the . . . unborn child during pregnancy.” *Id.* § 59.14(b)(1)(iv).

Possibly, the woman might be lucky enough to live near a Title X provider who—in accordance with the professional ethical obligations of medical providers—agrees to refer a woman seeking an abortion to an actual abortion clinic. Even then, the woman is not much closer to actually receiving a proper referral. One would think the provider could simply say, “We do not perform abortions. Title X does not allow Title X funds to be used to perform abortions. But here is a referral to an independent medical provider, who receives no Title X funds, who will help you.” But the Final Rule does not allow that. Instead, after referring the woman to a provider of prenatal care (as is mandatory), the provider may provide “[a] list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care)[.]” *Id.* § 59.14(b)(1)(ii). If the sympathetic counselor provides this list, HHS allows the list to include some providers “which also provide abortion as part of their comprehensive health care services.” *Id.* § 59.14(c)(ii). However, in what one imagines would come as a shock to this poor woman, the list is prohibited from including a majority of providers who actually provide abortion services. *Id.* At this point, the woman is staring at multiple names on a list. As is usual

⁴ It is difficult to comprehend that Congress would so adamantly require that all pregnancy counseling be nondirective, only to later allow the provider to refer a woman seeking an abortion to an adoption agency.

in the medical setting, she might ask the provider, whom she trusts, for a single recommendation. At this point, the provider may only say, “I’m sorry, I cannot help you.” In the agency’s zeal to limit any abortions, even legal abortions provided outside the Title X program, the Final Rule states, “Neither the list nor project staff may identify which providers on the list perform abortions.” *Id.*

The Gag Rule is remarkable in striving to make professional health care providers deaf and dumb when counseling a client who wishes to have a legal abortion or is even considering the possibility. The rule handcuffs providers by restricting their responses in such situations to providing their patient with a list of primary care physicians who can assist with their pregnancy without identifying the ones who might perform an abortion. Again, the response is required to be, “I can’t help you with that or discuss it. Here is a list of doctors who can assist you with your pre-natal care despite the fact that you are not seeking such care. Some of the providers on this list—but in no case more than half— may provide abortions services, but I can’t tell you which ones might. Have a nice day.”⁵ This is madness. Plaintiffs have shown what is reflected in the sophistry of the Final Rule itself—that they are likely to succeed on their claim that the Gag Rule is contrary to law. I turn now to the Separation Requirement.

As noted, the Separation Requirement requires physical and financial separation of Title X services and those services prohibited under the Final Rule. 84 Fed. Reg. at 7789 (to be codified at 42 C.F.R. § 59.15). Separation is required not only if the provider itself performs abortions, but when the provider performs any activities that, in HHS’s view, “promote . . . or support abortion as a method of family planning[.]” *Id.* at 7788-89 (to be codified at 42 C.F.R. §

⁵ This is as silly as it is insulting. I cannot imagine visiting my urologist’s office to request a vasectomy, only to be given a list of fertility clinics. I would think that my doctor had gone mad.

59.14). In short, any activity prohibited by the Gag Rule must have no connection, physically or financially, from activities allowed under the Final Rule. *See id.* at 7789 (to be codified at 42 C.F.R. § 59.15 (requiring separation of activities prohibited under Section 1008 as well as 42 C.F.R. §§ 59.13, 59.14, 59.16)).

To ensure that a Title X grantee is in compliance with the Separation Requirement, the Final Rule allows the agency to consider the following facts and circumstances:

- (a) The existence of separate, accurate accounting records;
- (b) The degree of separation from facilities (e.g. treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities;
- (c) The existence of separate personnel, electronic or paper-based health care records, and workstations; and
- (d) The extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent.

Id. at 7789 (to be codified at 42 C.F.R. § 59.15)

In explaining its reasoning for adding physical separation in addition to the previous requirement of financial separation, the agency does not once mention consideration of any limitations Congress imposed under the ACA. Instead, the agency focuses solely on Section 1008 and *Rust. Id.* at 7763-7767.

As noted, Congress passed the Affordable Care Act in 2010. The ACA spoke directly to HHS, prohibiting it from promulgating any regulation that:

- (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114.

HHS first argues that Plaintiffs waived any ACA-based challenge to the Final Rule. First, the court is skeptical that an agency may defend an action challenging the scope of the agency's authority solely with an argument that the plaintiff waived any such challenge. *See Sierra Club v. Pruitt*, 293 F. Supp. 3d 1050, 1061 (N.D. Cal. 2018) (noting “the waiver rule does not apply to preclude argument where the scope of the agency's power to act is concerned.”). HHS's waiver argument relies on the premise that, so long as no one specifically challenges the agency's authority during the notice and comment period, the agency has the freedom to act in blatant violation of its Congressional authorization.

Regardless, I conclude Plaintiffs have not waived any challenge based on the ACA. Waiver does not apply “if an agency has had the opportunity to consider the issue.” *Portland Gen. Elec. Co. v. Bonneville Power Admin.*, 501 F.3d 1009, 1024 (9th Cir. 2007). This is true even if a third party, as opposed to the plaintiffs, put the agency on notice by providing the agency the opportunity to correct its error. *Id.* Here, while not specifically pointing to 42 U.S.C. § 18114, multiple commenters objected under each prong of the statute. *See* AMA Reply, 11-12 n.3; ECF No. 119 (meticulously matching specific comments to each prong of 42 U.S.C. § 18114); *see also* States' Reply, 9 n.7; ECF No. 121 (same).

HHS's other arguments regarding why Section 18114 does not apply to Title X are unpersuasive. HHS argues that had Congress wanted to limit Title X, it would have listed the title in Section 18114. HHS also argues the restrictions are somehow “overbroad” or “open-ended.” Simply because Congress specifically sought to limit the general scope of HHS's rulemaking abilities, however, does not somehow render the limitations invalid. *See Bowen v.*

Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) (“It is axiomatic that an administrative

agency’s power to promulgate legislative regulations is limited to the authority delegated by Congress.”). That regulations issued by HHS 30 years ago might clash with limitations Congress later placed on HHS does not mean HHS may ignore the newer restrictions.

That Congress intended in Section 18114 to limit HHS’s rulemaking authority appears clear. Before delineating the six new restrictions, Congress stated, “Notwithstanding any other provision of this Act, the Secretary of Health and Human Services *shall not promulgate any regulation that . . .*” 42 U.S.C. § 18114. The Final Rule, of course, is a regulation promulgated by HHS. The agency argues the language, “Notwithstanding any other provision of this Act,” means Congress meant the limitations to apply only to regulations the ACA authorized HHS to implement. I disagree. That language merely indicates that the specific limitations in Section 18114 override any conflicting provisions of the ACA. *See Field v. Napolitano*, 663 F.3d 505, 511 (1st Cir. 2011) (noting that statute’s use of “Notwithstanding any other provision of law” “clearly signals the drafter’s intention that the provisions of ‘notwithstanding’ section override conflicting provisions of any other section”) (quoting *Cisneros v. Alpine Ridge Grp.*, 508 U.S. 10, 18 (1993)). The Supreme Court agrees that “notwithstanding” language indicates the drafter intended “to supersede all other laws” and that a “clearer statement is difficult to imagine.” *Cisneros*, 508 U.S. at 18 (citation omitted).

I conclude Plaintiffs have demonstrated the limitations in Section 18114 likely apply to the Final Rule. The first and second limitations prohibit HHS from implementing any regulation that: “(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; [or] (2) impedes timely access to health care services[.]” 42 U.S.C. § 18114. At this stage, there is at least a strong argument to be made that the Separation Requirement creates unreasonable barriers to Title X clients obtaining appropriate medical care and impedes their

timely access to such care. To ensure compliance with the rule, HHS encourages Title X providers to maintain one set of offices for Title X services and physically separate offices for any service prohibited by the Gag Rule. 84 Fed. Reg. at 7789. The provider should ensure the offices do not share entrances or exits, waiting rooms, or even websites. *Id.* The provider must ensure the separate offices maintain “[t]he existence of separate personnel, electronic or paper-based health care record, and workstations[.]” *Id.* Although the declarations indicate the financial burdens will severely strain already tight budgets, I also am mindful of the fact that many of the rules underlying the Separation Requirement would impinge on the ability of providers to engage in nondirective counseling, in contrast with the congressional mandate.

Even assuming, however, that the ACA does not apply to the Final Rule, or that the Separation Requirement does not create impermissible barriers to client care, Plaintiffs have demonstrated, at worst, serious questions going to the merits of their claims that the Final Rule is arbitrary and capricious. “Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the produce of agency expertise.” *Motor Vehicle Manufacturers Ass’n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Based on the record currently before the Court, the Final Rule appears to force medical providers to either drop out of the program or violate their codes of professional ethics. James L. Madara, MD, is a Medical Doctor, the Chief Executive Officer and Executive Vice President of the AMA, and an adjunct professor of pathology at Northwestern University. Madara Decl. ¶ 1; ECF No. 49. The AMA “is the largest professional association of physicians, residents, and

medical students in the United States.” *Id.* ¶ 5. To call the AMA the leading organization regarding medical ethics is practically an understatement. The AMA literally wrote the book on medical ethics. “The AMA has published the *Code of Medical Ethics of the American Medical Association* since 1847. This was the first modern national medical ethics code in the world and continues to be the most comprehensive and well respected code for physicians, world-wide.” *Id.*

¶ 13. Dr. Madera outlines several troubling aspects of the Final Rule:⁶

17. “Except in emergency situations in which a patient is incapable of making an informed decision, withholding information without the patient’s knowledge or consent is ethically unacceptable.” *Code of Medical Ethics* Opinion 2.1.3. *Withholding Information from Patients.*

18. Therefore, patients have the right “to receive information from their physicians and to have the opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives... [P]atients should be able to expect that their physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician’s objective professional judgment.” *Code of Medical Ethics* Opinion 1.1.3. *Patient Rights.* Further, patients have a right to “expect that their physician will cooperate in coordinating medically indicated care with other health care professionals[.]” *Id.* Finally, physicians should “[h]onor a patient’s request not to receive certain medical information.” *Code of Medical Ethics* Opinion 2.1.3. *Withholding Information from Patients.*

19. Physicians are ethically obligated to “[b]ase the decision or recommendation [to consult or refer] on the patient’s medical needs, as they would for any treatment recommendation, and consult or refer the patient to only health care professionals who have appropriate knowledge and skills and are licensed to provide the services needed.” *Code of Medical Ethics* Opinion 1.2.3. *Consultation, Referral, & Second Opinions.*

20. Within the treating relationship, the “physician must be sensitive to the imbalance of power in the patient-physician relationship, as well as to the patient’s vulnerability[, and] must not allow differences with the patient or family about political matters to interfere with the delivery of professional care.” *Code of Medical Ethics* Opinion 2.3.4. *Political Communications.*

⁶ Dr. Madera alerted HHS to the AMA’s concerns during the Final Rule’s notice and comment period. Madera Decl. ¶ 3 (citing July 31, 2018 letter—available at <http://www.regulations.gov/document?D=HHS-OS-2018-0008-179739>—from AMA to HHS).

Madara Decl. (ellipses and alterations in original).

Dr. Madera concludes that “the Final Rule would require doctors to violate each of these fundamental ethical and professional norms.”⁷ Madara Decl. ¶ 21. In examining the Final Rule, it is readily apparent how Dr. Madera reached his conclusion. The Final Rule, by requiring a referral for prenatal care to a woman seeking an abortion, and by requiring that the patient receive unnecessary counseling in addition to abortion counseling, mandates that providers provide medical information that patient does not need and, almost certainly, does not request. Those requirements also prohibit the physician from basing the counseling or referral on the patient’s actual medical needs. By requiring that any list provided for an abortion referral contain some providers who do not perform abortions, and by prohibiting physicians from identifying the abortion providers, the Final Rule “is an instruction to physicians to intentionally mislead patients, which, if followed, is an instruction for physicians to directly violate the *Code of Medical Ethics*[.]”⁸ Madera Decl. ¶ 25 (citing Opinions 1.1.1, 1.1.3, 1.2.3, 2.1.3, and 2.3.4).

As the Final Rule contradicts this persuasive evidence from the leading expert on medical ethics, HHS must have a plausible explanation outlining its rationale for rejecting the evidence and reaching a different conclusion. *Motor Vehicle Manufacturers Ass’n*, 463 U.S. at 43. Once again, however, HHS’s justifications are lacking. HHS simply brushes aside any concerns and, in a generic and conclusory fashion, asserts the Final Rule violates no ethical obligations. As HHS’s response to comments is relatively brief, and demonstrates the agency never addressed,

⁷ Although this opinion only references Dr. Madera’s declaration, Plaintiffs presented numerous expert opinions, each essentially arriving at the same conclusion reached by Dr. Madera. Other than relying on the Final Rule itself and *Rust*, HHS provided no evidence in rebuttal.

⁸ Should the ACA in fact apply to the Final Rule, the objections noted by Dr. Madera indicate the Gag Rule likely violates each of the six limitations Congress imposed on HHS’s rulemaking authority.

and does not appear to have even considered, the specific objections noted above, I include

HHS's entire explanation:

The Department disagrees with commenters contending the proposed rule, to the extent it is finalized here, infringes on the legal, ethical, or professional obligations of medical professionals. Rather, the Department believes that the final rule adequately accommodates medical professionals and their ethical obligations while maintaining the integrity of the Title X program. In general, medical ethics obligations require the medical professional to share full and accurate information with the patient, in response to her specific medical condition and circumstance. Under the terms of this final rule, a physician or APP may provide nondirective pregnancy counseling to pregnant Title X clients on the patient's pregnancy options, including abortion. Although this occurs in a postconception setting, Congress recognizes and permits pregnancy counseling within the Title X program, so long as such counseling is nondirective. The permissive nature of this nondirective pregnancy counseling affords the physician or APP the ability to discuss the risks and side effects of each option, so long as this counsel in no way promotes or refers for abortion as a method of family planning. It permits the patient to ask questions and to have those questions answered by a medical professional. Within the limits of the Title X statute and this final rule, the physician or APP is required to refer for medical emergencies and for conditions for which non-Title X care is medically necessary for the health and safety of the mother or child.

84 Fed. Reg. at 7724.

Although acknowledging that medical ethics "require the medical professional to share full and accurate information with the patient, in response to her specific medical condition and circumstance," the agency nowhere squares that requirement with the Final Rule's requirement that all abortion counseling provide information not in fact specific to the patient's medical needs. Despite acknowledging providers must share accurate information with the patient, HHS requires any referral for abortion contain, at minimum, an equal amount of information that is of no use to the pregnant woman. That HHS appears to have failed to seriously consider persuasive evidence that the Final Rule would force providers to violate their ethical obligations suggests that the rule is arbitrary and capricious. *See Tesoro Alaska Petroleum Co. v. F.E.R.C.*, 234 F.3d

1286, 1294 (D.C. Cir. 2000) (“The Commission’s failure to respond meaningfully to the evidence renders its decisions arbitrary and capricious. Unless an agency answers objections that on their face appear legitimate, its decision can hardly be said to be reasoned.”).

The Final Rule could well be arbitrary and capricious in other aspects as well. Plaintiffs argue HHS failed to adequately account for the impact the Final Rule will have on women, particularly women in rural areas. Because the Final Rule forces providers to choose between violating ethical obligations or leaving the Title X program, many providers, including Planned Parenthood, informed HHS during the notice and comment period that if HHS implemented the proposed regulation, the providers would exit the program. Planned Parenthood serves approximately 40% of all Title X patients. Custer Decl. ¶ 8. Planned Parenthood’s importance to the program is difficult to overstate. “Rural and sparsely populated areas will be harmed most. In those areas, Planned Parenthood is often the only safety-net reproductive health care provider available to patients seeking publicly funded services. In more than half of the counties where Planned Parenthood health centers were located in 2015 (238 of 415), Planned Parenthood served at least half of the women by obtaining publicly supported contraceptive services from a safety-net health center. In nearly 10% of the rural counties (38 of 415), Planned Parenthood was the only safety-net family planning center.” *Id.* ¶ 37 (internal footnotes omitted). Planned Parenthood’s absence would create a vacuum for family planning services. “Other safety-net clinics that are not forced from Title X will not be able to pick up the slack and provide care to the 1.6 million women, men, and adolescents who today receive vital family planning services from Planned Parenthood health centers that participate in the Title X program.” *Id.* ¶ 54.

The elimination of Title X providers would be detrimental to the public health. Many women, but especially low-income women, have no interactions with health care providers

outside of a Title X provider. Brandis Decl. ¶ 18. The Final Rule will increase not only unintended (and riskier) pregnancies, *id.* ¶ 23, but abortions as well, *id.* ¶ 26. Reduced access to Title X health centers will result in less testing, increased STIs, and more women suffering adverse reproductive health symptoms. *Id.* ¶ 29.

One would imagine HHS relied on studies and research to determine the impact on women's health should a provider of nearly half of all Title X services withdraw from the program. If HHS in fact relied on something, it is not shown in this record. In fact, HHS does not acknowledge the Title X program stands to be cut in half on May 3, 2019. Instead, HHS baldly asserts that "these final rules will contribute to more clients being served, gaps in service being closed, and improved client care" 84 Fed. Reg. at 7723. HHS anticipates new providers will step forward, providers who earlier stayed away from the program due to abortion-related concerns. But HHS fails to show its work. There is no transparency and no way to find out what, if anything, HHS based its assumptions on. The record is devoid of comments from potential providers ready, willing, and able to fill the 1.6 million woman gap in coverage left by Planned Parenthood's exit. Again, when HHS issued the above findings, it knew that, should it implement the Final Rule, it would lose the provider of nearly half of all Title X services within two months. It could be that HHS relied on some internal reports or studies. But on this record, HHS's unsupported conclusions appear to run "counter to the evidence before the agency." *State Farm*, 463 U.S. at 43.

As Plaintiffs have demonstrated a likelihood of success on the merits of their claims that the Final Rule is contrary to law and arbitrary and capricious. I turn next to whether Plaintiffs have shown "that irreparable injury is likely in the absence of an injunction." *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (quoting *Winter*, 555 U.S. at 22). As HHS failed to introduce

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any evidence on this issue, the only evidence before me is that if the Final Rule goes into effect, many Title X providers will exit the program because, amongst other reasons, the Final Rule violates established standards of medical ethics. Notably, Planned Parenthood will exit Title X if the rule is implemented. Kost Decl. ¶ 109; ECF No. 53. Although many other providers state they too will exit the program, Planned Parenthood is of unique importance because its “health centers serve 41% of women who rely on Title X sites for contraceptive care.” *Id.* ¶ 110. In Vermont, Planned Parenthood is the lone provider of Title X services. Holmes Decl. ¶¶ 6, 19. In fact, every state plaintiff submitted declarations stating they will lose much, if not all of their current Title X funding should the rule go into effect. States’ Br. 35-37. The likely harm to the public health, in the form of an increase in sexually transmitted disease and unexpected pregnancies, is not speculative. Brandis Decl. ¶¶ 31, 47. This harm to the public health will have a detrimental economic impact on the states. The Ninth Circuit has recognized that such economic harm (stemming from likely cuts to birth control), and supported by evidence analogous to the declarations provided here, sufficiently demonstrates a threat of harm to a state’s economic interest. *Azar*, 911 F.3d at 571-73. Additionally, the *Azar* court concluded such harm is sufficient to establish a likelihood of irreparable injury. *Id.* at 581 (noting that because the APA permits relief “other than money damages,” such economic harm was irreparable) (quoting 5 U.S.C. § 702)).

Additionally, the balance of the equities and the public interest tips sharply in favor of the Plaintiffs. “The public interest is served by compliance with the APA.” *Id.* “There is generally no public interest in the perpetuation of unlawful agency action.” *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016). There is ample evidence at this stage that the Final Rule is unlawful. The un rebutted evidence demonstrates, at this stage of the proceedings, that the

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Final Rule would force medical providers to violate their ethical and professional obligations. Additionally, there is little harm in preserving the status quo. The current regulations have been in place for nearly 50 years and have an excellent track record. With such substantial questions surrounding the legality of the Final Rule, and with the potential for great harm to low-income women in particular should the rule go into effect, these prongs of the preliminary injunction standard tilt quite heavily in Plaintiffs' favor.

The Ninth Circuit recently outlined concerns regarding overbroad injunctions. *See Azar*, 911 F.3d at 583-84 (noting detrimental impact on development of law and effects on non-parties). In crafting an injunction, “[t]he scope of remedy must be no broader and no narrower than necessary to redress the injury show by the plaintiff[s].” *Id.* at 584. Here, Planned Parenthood operates in 48 states. Plaintiff AMA’s member physicians practice and reside in every state in the country. Madara Decl. ¶ 7. AMA members (physicians and licensed health care practitioners) provide counseling to pregnant women in the Title X program. *Id.* There is ample evidence regarding the potential harm to the public health of not only the plaintiff states, but the nation. Brandis Decl. ¶¶ 35-37, 45-54. Given that the harm to Plaintiffs would occur in every state, and considering the balance of equities and the fact that Plaintiffs have demonstrated significant likelihood on the merits of their claims that the Final Rule is contrary to law, a nationwide injunction is appropriate.⁹

⁹ On Friday, HHS filed a response to a notice filed Thursday regarding an injunction issued by Judge Bastian in the Eastern District of Washington. Judge Bastian entered a nationwide injunction prohibiting HHS from implementing the Final Rule. HHS argues there is no longer any likelihood of imminent harm. I disagree. As I understand it, the order submitted as an exhibit to ECF No. 137 is a preliminary ruling which Judge Bastian intends to follow with a final opinion sometime before May 3, 2019. Additionally, the Court understands Judge Chen in the Northern District of California issued an injunction last Friday restraining HHS from implementing the rule in California. HHS here states it is considering appealing Judge Bastian’s injunction, and asks this Court to stay this matter. Specifically, HHS states that “Should the government seek and obtain a stay of the Washington Order, the Plaintiffs could move this Court to lift the stay, at which point the Court would be in a position to rule promptly.” ECF No. 138, 3. The Court will allow a full briefing regarding whether a stay is appropriate. At this point, a ruling on the pending motion

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CONCLUSION

Plaintiffs' motions for a preliminary injunction are GRANTED in full. Defendants, and their agents and officers, are restrained from implementing or enforcing any portion of the Final Rule detailed in 84 Fed. Reg. 7714-7791 (March 4, 2019) and shall preserve the status quo under the current regulations pending further order from the Court. No bond is required.

IT IS SO ORDERED.

DATED this 29 day of April, 2019.



Michael J. McShane
United States District Judge

is appropriate. Planned Parenthood provides service for nearly half of the entire Title X program. They are a plaintiff in this action, not the action pending before Judge Bastian.

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2019 WL 1877392

Only the Westlaw citation is currently available.
United States District Court, N.D. California.

STATE OF CALIFORNIA, Plaintiff,

v.

ALEX AZAR, et al., Defendants.

[ESSENTIAL ACCESS HEALTH, INC.](#), et al.,

Plaintiffs,

v.

ALEX M. AZAR II, et al., Defendants.

Case No. 19-cv-01184-EMC, Case No. 19-cv-01195-
EMC

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Docket No. 26, C-19-1184, Docket No. 25, C-19-
1195

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Filed 04/26/2019

**ORDER GRANTING IN PART AND DENYING IN
PART PLAINTIFFS' MOTIONS FOR
PRELIMINARY INJUNCTION**

[EDWARD M. CHEN](#) United States District Judge

*1 Title X of the Public Health Service Act provides federal funding for family-planning services. In the quarter-century since 1993, the Department of Health and Human Services' ("HHS") guidelines, while prohibiting funding of abortion services pursuant to Title X, have required Title X grantees to provide neutral, factual counseling to pregnant clients and to maintain financial separation between their Title X activities and their abortion services. This permitted grantees to operate effectively while complying with Title X. On March 4, 2019, HHS promulgated new regulations implementing Title X which substantially changes those guidelines in a manner that jeopardizes the provision of essential and counseling and care to thousands of women. *See* [84 Fed. Reg. 7714 \(2019\)](#) (the "Final Rule"). According to Plaintiffs, the Final Rule will create daunting barriers to California women seeking timely, effective reproductive health care, impose medically and ethically unsound

restrictions on Title X providers attempting to provide patient-centered care, and inflict severe public health consequences and costs on the State. They contend the Final Rule violates recent acts of Congress, substantive and procedural provisions of the Administrative Procedures Act ("APA"), and the First and Fifth Amendments to the U.S. Constitution.

The Final Rule goes into effect on May 3, 2019. Plaintiffs in these coordinated actions, the State of California and Essential Access Health, seek to preliminarily enjoin the implementation of the Final Rule.

Unless enjoined, the Final Rule will irreparably harm individual patients and public health in California as a whole. The Final Rule commands medical professionals to provide incomplete and misleading information to women seeking to terminate their pregnancies contrary to what patients want and need, delaying and potentially frustrating their attempts to obtain time-sensitive care, and thereby jeopardizing their health and welfare. The Final Rule threatens to decimate the network of Title X providers in California and drastically restrict patients' access to a wide range of vital services, including contraceptive resources and screenings for sexually transmitted infections, reproductive [cancers](#), and HIV. As a result, the Final Rule is likely to inflict significant public health consequences and costs on the State and frustrate Essential Access's organizational mission to promote access to quality healthcare. In contrast, Defendants are unable to articulate any real harm they will suffer if the Final Rule is preliminarily enjoined during the pendency of this action.

Plaintiffs have shown that the Final Rule likely violates Congressional directives that Title X providers must be permitted to give pregnant patients neutral, factual information regarding the full range of their medical options, and must not be compelled to act in a way that is contrary to medical ethics. The record evidence indicates that HHS promulgated the Final Rule, which represents a sharp break from prior policy, without engaging in any reasoned decisionmaking. In particular, HHS cited speculative, unsubstantiated fears about the misuse of Title X funds as justification for its change in policy and touted anticipated benefits of the Final Rule that have no basis in the record, while cursorily dismissing overwhelming evidence of the significant adverse impact the Rule will have. The Final Rule is thus contrary to law and arbitrary and capricious.

*2 Having considered the parties' briefs and accompanying submissions, as well as the oral argument

of counsel and amici briefs filed herein, the Court finds that Plaintiffs have established they are likely to succeed on the merits on several of their claims, are likely to suffer irreparable injury if the Final Rule is not enjoined, and the balance of hardships and the public interest tip sharply in favor of granting injunctive relief. Accordingly, Plaintiffs' motions for a preliminary injunction are **GRANTED in part and DENIED in part.**¹ The Court enjoins implementation of the Final Rule but limits the injunction to California.

I. BACKGROUND

A. Statutory and Regulatory Background

1. Title X

The Public Health Service Act ("PHSA"), an expansive statutory scheme that consolidated existing public health laws and established various agencies and grant programs to support health care and research, was enacted in 1944. In 1970, Congress amended the PHSA to add "Title X—Population Research and Voluntary Family Planning Programs." [Pub. L. No. 91-572, § 6, 84 Stat. 1504](#), 1506–08 (1970) (codified at [42 U.S.C. §§ 300–300a-6](#)). Title X authorizes the Secretary of HHS "to make grants to and enter into contracts with public or nonprofit private entities 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." [42 U.S.C. § 300\(a\)](#). Such grants and contracts must "be made in accordance with such regulations as the Secretary may promulgate." *Id.* § 300a-4. Congress explained that its purpose in enacting Title X was:

- a. to assist in making comprehensive voluntary family planning services readily available to all persons desiring such services;
- b. to coordinate domestic population and family planning research with the present and future needs of family planning programs;
- c. to improve administrative and operational supervision of domestic family planning services and of population research programs related to such

services;

d. to enable public and nonprofit private entities to plan and develop comprehensive programs of family planning services;

e. to develop and make readily available information (including educational materials) on family planning and population growth to all persons desiring such information;

f. to evaluate and improve the effectiveness of family planning service programs and of population research; [and]

g. to assist in providing trained manpower needed to effectively carry out programs of population research and family planning services

[Pub. L. No. 91-572 § 2, 84 Stat. 1504.](#)

Per Section 1008 of the PHSA, "[n]one of the funds appropriated under [Title X] shall be used in programs where abortion is a method of family planning." [42 U.S.C. § 300a-6.](#)

2. The 1971 Regulations, 1981 Guidance, 1988 Regulations, and *Rust v. Sullivan*

*3 Consistent with Section 1008, HHS has never permitted Title X grantees to use Title X funds to perform or subsidize abortions. *See* [42 C.F.R. §§ 59.5\(a\)\(5\), 59.9 \(1986\)](#). However, the agency had long interpreted Title X to allow grantees to provide pregnant women with nondirective counseling and referrals about their medical options, including abortion. The initial regulations, issued in 1971, stated that Section 1008 only required that a Title X "project will not provide abortions as a method of family planning." [36 Fed. Reg. 18,465, 18,466 \(1971\)](#). "During the mid-1970s, HHS General Counsel memoranda made a further distinction between directive ('encouraging or promoting' abortion) and nondirective ('neutral') counseling on abortion, prohibiting the former and permitting the latter." *Nat'l Family Planning & Reprod. Health Ass'n, Inc. v. Sullivan*, [979 F.2d 227, 229 \(D.C. Cir. 1992\)](#). This distinction was reaffirmed in 1981, when HHS issued guidelines "requir[ing] nondirective 'options counseling' [*sic*] on pregnancy termination (abortion), prenatal care, and adoption and foster care when a woman with an unintended pregnancy requests information on her options, followed by referral for these services if she so requests." [53 Fed. Reg. 2922, 2923](#)

(1988). Thus, early on, HHS distinguished nondirective counseling (and referrals) from the actual provision of abortion services, permitting the former but prohibiting the latter.

That policy was reversed in 1988 when HHS promulgated new regulations to provide “‘clear and operational guidance’ to grantees about how to preserve the distinction between Title X programs and abortion as a method of family planning.” *Id.* at 2923–24. The term “family planning” was redefined to encompass solely “preconceptional counseling, education, and general reproductive health care,” while expressly excluding “pregnancy care (including obstetric or prenatal care).” 42 C.F.R. § 59.2 (1989).

The thrust of the 1988 regulations was reflected in three main provisions. First, they provided that a “Title X project may not provide counseling concerning the use of abortion as a method of family planning or provide referral for abortion as a method of family planning,” even in response to a client’s specific request. *Id.* § 59.8(a)(1). Second, the regulations prohibited a Title X project from engaging in any activities that “encourage, promote or advocate abortion as a method of family planning.” *Id.* § 59.10(a). Third, Title X projects were required to be “physically and financially separate” from prohibited abortion activities. *Id.* § 59.9. The regulations enumerated nonexclusive factors for the Secretary of HHS to consult in determining whether the separation requirement was met, including the existence of separate accounting records and separate personnel, and the degree of physical separation of the project from facilities for prohibited activities. *Id.* The regulations made clear that “[m]ere bookkeeping separation of Title X funds from other monies is not sufficient.” *Id.*

The 1988 regulations were subject to legal challenge, and were upheld by the Supreme Court against a facial challenge by Title X grantees in *Rust v. Sullivan*, 500 U.S. 173 (1991). The *Rust* plaintiffs objected to the regulations on statutory and constitutional grounds. They argued that the regulations were arbitrary and capricious and exceeded the Secretary’s authority under Title X, that the regulations’ proscription of abortion counseling and referral violated the First Amendment, and that the regulations violated a woman’s Fifth Amendment right to choose whether to terminate her pregnancy. *Id.* at 183, 192, 201.

The Supreme Court found none of these claims availing. It rejected the plaintiffs’ first statutory claim after applying *Chevron* deference to the Secretary’s construction of Title X. The Court determined that

statutory text and legislative history of Title X were ambiguous regarding abortion counseling and referral as well as the separation of Title X and non-Title X services. *Id.* at 184 (“The language of § 1008—that ‘[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning’—does not speak directly to the issues of counseling, referral, advocacy, or program integrity.”). In the face of that ambiguity, the Court decided that the Secretary’s construction of the statute “to require a ban on counseling, referral, and advocacy within the Title X project” was reasonable, noting that the “broad language” of “§ 1008 prohibits the use of Title X funds ‘in programs where abortion is a method of family planning’ ” and that “the legislative history is ambiguous and fails to shed light on relevant congressional intent.” *Id.* at 184–85. Similarly, the Court ruled that the Secretary’s construction of Title X to require physical and financial separation between Title X projects and abortion activities was permissible. *Id.* at 188–90. Importantly, even after finding the 1988 regulations facially reasonable under *Chevron*, the Court required the Secretary to justify his change of interpretation from the prior rules with a “reasoned analysis.” *Id.* at 187 (quoting *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41 (1983)). In this regard, the Court observed that the Secretary’s decision to reverse course from the prior regulations was justified in part because it responded to “critical reports of the General Accounting Office (GAO) and the Office of the Inspector General (OIG) that prior policy failed to implement properly the statute and that it was necessary to provide ‘clear and operational guidance to grantees about how to preserve the distinction between Title X programs and abortion as a method of family planning,’ ” as well as “client experience under the prior policy” and “a shift in attitude against the elimination of unborn children by abortion.” *Id.* (quoting 53 Fed. Reg. at 2923–24).

*4 *Rust* further held that the regulations did not “violate the First Amendment by impermissibly discriminating based on viewpoint” because “[t]he Government can, without violating the Constitution, selectively fund a program to encourage certain activities it believes to be in the public interest, without at the same time funding an alternative program which seeks to deal with the problem in another way.” *Id.* at 192–93. The Court noted its previous holding that “the government may ‘make a value judgment favoring childbirth over abortion, and ... implement that judgment by the allocation of public funds.’ ” *Id.* (quoting *Maher v. Roe*, 432 U.S. 464, 474 (1977)) (alteration in original). *Rust* thus determined that “[t]he Secretary’s regulations do not force the Title X grantee to give up abortion-related speech; they merely

require that the grantee keep such activities separate and distinct from Title X activities.” *Id.* at 196. Grantees “remain[ed] free ... to pursue abortion-related activities when they [we]re not acting under the auspices of the Title X project.” *Id.* at 198. The Court cautioned, however, that it was “not ... suggest[ing] that funding by the Government, even when coupled with the freedom of the fund recipients to speak outside the scope of the Government-funded project, is invariably sufficient to justify Government control over the content of expression.” *Id.* at 199.

Lastly, the Court ruled that the 1988 regulations did not impermissibly burden a woman’s Fifth Amendment right to choose whether to terminate her pregnancy. Citing the principle that “the Due Process Clauses generally confer no affirmative right to governmental aid,” the Court held that “[t]he Government has no constitutional duty to subsidize an activity merely because the activity is constitutionally protected and may validly choose to fund childbirth over abortion.” *Id.* at 201 (quoting *Webster v. Reprod. Health Servs.*, 492 U.S. 490, 507 (1989)). In support of this holding, *Rust* reasoned that “[t]he difficulty that a woman encounters when a Title X project does not provide abortion counseling or referral leaves her in no different position than she would have been if the Government had not enacted Title X.” *Id.* at 202. The Court also found unpersuasive the plaintiffs’ contention that “the regulations violate a woman’s Fifth Amendment right to medical self-determination and to make informed medical decisions free of government-imposed harm” by “depriving a Title X client of information concerning abortion as a method of family planning.” *Id.* The Court observed that under the regulations, “a doctor’s ability to provide, and a woman’s right to receive, information concerning abortion and abortion-related services outside the context of the Title X project remains unfettered.” *Id.* at 203.

3. 1993 Suspension of the 1988 Regulations and Promulgation of the 2000 Regulations

Although they survived legal challenges, the 1988 regulations were never fully implemented. The Secretary suspended the regulations in 1993 “based, in part, upon her conclusion that the ‘Gag Rule’ is an inappropriate implementation of the Title X statute because it unduly restricts the information and other services provided to individuals under this program.” 58 Fed. Reg. 7462, 7462 (1993). As a result, after 1993, Title X grantees returned to operating under the 1981 guidelines.

In 2000, HHS formally issued new regulations “revoking the regulations published on February 2, 1988” and largely restoring the 1981 regulatory scheme. 65 Fed. Reg. 41270 (2000); 65 Fed. Reg. 41281 (2000). Most notably, under the 2000 regulations, Title X grantees were required to “[o]ffer pregnant women the opportunity to be provided information and counseling regarding ... [p]regnancy termination” and “provide neutral, factual information and nondirective counseling on each of the options, and referral” upon request. 42 C.F.R. § 59.5(a)(5) (July 3, 2000). Grantees’ non-Title X abortion activities had to be “separate and distinct” from Title X activities, but “[c]ertain kinds of shared facilities [we]re permissible, so long as it [wa]s possible to distinguish between the Title X supported activities and non-Title X abortion-related activities.” 65 Fed. Reg. at 41281. For example, common waiting rooms and staff were permissible, as long as the costs and salaries were properly pro-rated and allocated. *Id.* The agency provided the following explanation for doing away with the physical separation requirement:

*5 If a Title X grantee can demonstrate by its financial records, counseling and service protocols, administrative procedures, and other means that—within the identified set of Title X-supported activities—promotion or encouragement of abortion as a method of family planning does not occur, then it is hard to see what additional statutory protection is afforded by the imposition of a requirement for “physical” separation. Indeed, in the light of the enforcement history noted above, it is not unreasonable to say that the standard of “physical” separation has, as a practical matter, had little relevance or applicability in the Title X program to date. Moreover, the practical difficulty of drawing lines in this area, both as experienced prior to 1988 and as evident in the history of the Gag Rule itself, suggests that this legal interpretation is not likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services.

65 Fed. Reg. at 41276.

key provisions are detailed below.

4. Statutory Developments

Two statutory developments since *Rust* are germane to this case. First, in every year since 1996, Congress has specified in HHS appropriations acts (part of annual omnibus appropriations acts containing a subsection specific to HHS funding) that “amounts provided to [Title X] projects under such title shall not be expended for abortions, [and] that *all pregnancy counseling shall be nondirective.*” *E.g.*, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, [Pub. L. No. 115-245](#), Div. B, Tit. II, 132 Stat 2981, 3070–71 (2018) (emphasis added).

Second, in Section 1554 of the Affordable Care Act (“ACA”), enacted in 2010, Congress directed that HHS:

shall not promulgate any regulation that—

- (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
- (2) impedes timely access to health care services;
- (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
- (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
- (5) violates the principles of informed consent and the ethical standards of health care professionals; or
- (6) limits the availability of health care treatment for the full duration of a patient’s medical needs.

[42 U.S.C. § 18114](#). As discussed below, these laws affect the enforcement of Title X.

B. The Final Rule

On March 4, 2019, HHS promulgated the Final Rule that is the subject of this suit. [84 Fed. Reg. 7714](#). The Final Rule represents a sharp break from the 2000 regulations, and a return in many aspects to the 1988 regulations. Its

1. Restrictions on Abortion Counseling and Referrals

The Final Rule contains several overlapping provisions regarding abortion counseling. It directs that Title X grantees may “[n]ot provide, promote, refer for, or support abortion as a method of family planning.” [42 C.F.R. § 59.5\(a\)\(5\) \(2019\)](#).² Similarly, it provides that “[a] Title X project may not encourage, promote or advocate abortion as a method of family planning.” § 59.16(a)(1). And “[a] Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion.” § 59.14(a). The Final Rule does not define what it means to “encourage,” “promote,” or “support” abortions. Nor does it fully illuminate the lines between permissible provision of information and impermissible encouragement, promotion, and support.

However, when a Title X client is confirmed to be pregnant, the Final Rule requires that the client “shall be referred to a health care provider for medically necessary prenatal health care.” § 59.14(b)(1). Such referral is mandated even if the client has decided not to carry the pregnancy to term. The “Title X provider may”—but is not required to—provide “[n]ondirective pregnancy counseling.” *Id.* That counseling can only be “provided by physicians or advanced practice providers [(“APPs”)],” *id.*, defined as “a medical professional who receives at least a graduate level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel patients,” § 59.2. As a result, medical professionals without a graduate level degree, such as registered nurses or licensed practical nurses, cannot provide such counseling.

*6 The Final Rule forbids Title X grantees from making referrals for abortion services. *See* [§ 59.5\(a\)\(5\)](#) (A Title X project “must [n]ot provide, promote, refer for, or support abortion as a method of family planning.”); § 59.14(a) (“A Title X project may not ... refer for ... abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion.”). Even if a client specifically requests a referral to an abortion provider, the Title X project can at most provide “[a] list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care).” § 59.14(b)(1)(ii), (c)(2). The list cannot include specialty clinics that do not also provide comprehensive primary health care. Further, the referral list “may be limited to those that do not provide

abortion.” § 59.14(c)(2). If the referral list includes abortion providers, those providers may not comprise “the majority” of the providers on the list, and “[n]either the list nor project staff may identify which providers on the list perform abortion.” *Id.* Hence, a Title X project may provide a client seeking an abortion a referral list of only providers who do not perform abortions without so indicating. A Title X project responding to a client’s request for an abortion referral can, at most, provide a list on which more than half of the providers do not provide abortions. And the project cannot tell the patient which of the providers actually performs abortions. With respect to medical emergencies, the Final Rule states: “In cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of medical services needed to address the emergency.” § 59.14(b)(2). The Final Rule provides as the single example of a qualifying emergency “an ectopic pregnancy.” § 59.14(e)(2).

These counseling and referral restrictions represent a sharp break from the 2000 regulations, as well as the prior 1981 guidelines effective since 1993. Until now, Title X grantees have been required³ to offer pregnant women nondirective pregnancy counseling and referral upon request. 42 C.F.R. § 59.5(a)(5). Grantees were not required to refer a woman who did not intend to continue her pregnancy to prenatal care, and no restrictions were placed on referral lists.

2. Requirement of Physical and Financial Separation

Under the Final Rule, “[a] Title X project must be organized so that it is physically and financially separate ... from activities which are prohibited under section 1008 of the Act and §§ 59.13, 59.14, and 59.16 of these regulations from inclusion in the Title X program.” § 59.15. “In order to be physically and financially separate, a Title X project must have an objective integrity and independence from prohibited activities,” and “[m]ere bookkeeping separation of Title X funds from other monies is not sufficient.” *Id.* The Secretary will determine whether such objective integrity and independence exist by looking to relevant factors that include: “The existence of separate, accurate accounting records”; “[t]he degree of separation [of] facilities (e.g., treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites); “[t]he existence of separate personnel, electronic or paper-based health care records, and workstations”; and the “extent to which signs and other forms of identification of the Title X project are

present, and signs and material referencing or promoting abortion are absent.” *Id.*

The new separation requirements again represent a marked departure from the current rule. Under the 2000 regulations, grantees’ abortion activities were required to be financially separate from their Title X activities, but “[c]ertain kinds of shared facilities [we]re permissible, so long as it [wa]s possible to distinguish between the Title X supported activities and non-Title X abortion-related activities.” 65 Fed. Reg. at 41281. For example, common waiting rooms and staff were permissible, as long as the costs and salaries were properly pro-rated and allocated. *Id.*

3. Removal of Requirement that Family Planning Methods and Services be “Medically Approved”

Previous Title X regulations required projects to “[p]rovide a broad range of acceptable and effective *medically approved* family planning methods ... and services.” 42 C.F.R. § 59.5(a)(1) (2000) (emphasis added). The Final Rule removes the “medically approved” language; it simply requires Title X projects to “[p]rovide a broad range of acceptable and effective family planning methods ... and services.” § 59.5(a)(1).

4. Encouragement of Family Participation

The Final Rule requires Title X grantees to “[e]ncourage family participation in the decision to seek family planning services; and, with respect to each minor patient, ensure that the records maintained document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).” § 59.5(a)(14).

*7 The 2000 regulations contained no such requirement, although Title X itself provides that “[t]o the extent practical, entities which receive grants or contracts under this subsection shall encourage family participation in projects assisted under this subsection.” 42 U.S.C. § 300(a).

C. Procedural Background

The motions currently before the Court arise from two lawsuits. The first is brought by the State of California (“California”). See *State of California v. Azar et al.*, No. 3:19-cv-1184-EMC (N.D. Cal. filed March 4, 2019) (“California”), Docket No. 1 ¶ 1. The second is brought by Essential Access Health, Inc. and Dr. Melissa Marshall (collectively, “Essential Access”). See *Essential Access Health, Inc., et al. v. Azar et al.*, No. 3:19-cv-1195-EMC (N.D. Cal. filed March 4, 2019) (“Essential Access”), Docket No. 1 ¶¶ 15–16. California’s Title X network is the largest in the nation. *California* Docket No. 1 ¶ 3. Essential Access is a nonprofit corporation that is California’s sole Title X grantee and administers the state’s Title X program. *Essential Access* Docket No. 1 ¶ 15. Dr. Marshall is the Chief Executive Officer of CommuniCare Health Centers in Yolo County, California, which has been part of the State’s Title X network since 1993. *Id.* ¶ 16. California, Essential Access Health, and Dr. Marshall are hereinafter referred to collectively as “Plaintiffs.” Defendants are HHS and Alex M. Azar, II, sued in his official capacity as Secretary of HHS.

California and Essential Access filed their respective motions for preliminary injunction on March 21, 2019. *California* Docket No. 26 (“California Mot.”); *Essential Access* Docket No. 25 (“Essential Mot.”). Defendants filed a consolidated opposition on April 8, 2019. *California* Docket No. 61 (“Opp.”). Plaintiffs filed replies on April 11, 2019. *California* Docket No. 84 (“California Reply”); *Essential Access* Docket No. 63 (“Essential Reply”). The Court held a hearing on the motions on April 18, 2019.

II. LEGAL STANDARD

A preliminary injunction is a matter of equitable discretion and “an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.” *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). Its “purpose ... is to preserve the status quo and the rights of the parties until a final judgment issues in the cause.” *U.S. Philips Corp. v. KBC Bank N.V.*, 590 F.3d 1091, 1094 (9th Cir. 2010).

A party seeking a preliminary injunction must meet one of two variants of the same standard. The traditional *Winter* standard requires the movant to show “that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an

injunction is in the public interest.” *Winter*, 555 U.S. at 20. Under the “sliding scale” variant of the same standard, “if a plaintiff can only show that there are ‘serious questions going to the merits’—a lesser showing than likelihood of success on the merits—then a preliminary injunction may still issue if the ‘balance of hardships tips sharply in the plaintiff’s favor,’ and the other two *Winter* factors are satisfied.” *All. for the Wild Rockies v. Pena*, 865 F.3d 1211, 1217 (9th Cir. 2017) (emphasis in original) (quoting *Shell Offshore, Inc. v. Greenpeace, Inc.*, 709 F.3d 1281, 1291 (9th Cir. 2013)). In other words, irrespective of the robustness of the showing on the merits required, a plaintiff must demonstrate it is likely to suffer irreparable injury in the absence of preliminary relief. Accordingly, the Court begins by addressing that factor.

III. DISCUSSION

A. Likelihood of Irreparable Harm, the Balance of Equities, and the Public Interest

*8 The record evidence establishes that the irreparable injury, balance of hardships, and public interest factors tip sharply in Plaintiffs’ favor. *All. for the Wild Rockies*, 865 F.3d at 1217.

1. Harm to California’s Public Health and Essential Access’s Organizational Mission

Plaintiffs are likely to suffer several forms of irreparable harm unless the Final Rule is enjoined pending resolution of this case on the merits. The first type of harm is to California’s public health and to Essential Access’s organizational mission to promote access to high-quality healthcare. See *State v. Bureau of Land Mgmt.*, 286 F. Supp. 3d 1054, 1074 (N.D. Cal. 2018) (finding irreparable harm from agency rule that “will have irreparable consequences for public health”) (citing *Sierra Club v. U.S. Dep’t of Agric., Rural Utilities Serv.*, 841 F. Supp. 2d 349, 358–59 (D.D.C. 2012)); *Valle del Sol Inc. v. Whiting*, 732 F.3d 1006, 1029 (9th Cir. 2013) (finding irreparable harm where “organizational plaintiffs have shown ongoing harms to their organizational missions as a result of the statute”); *League of Women Voters of United States v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016) (holding that

obstacles that “make it more difficult for the [organizations] to accomplish their primary mission ... provide injury for purposes both of standing and irreparable harm”).

California’s efforts to advance its public health objectives by “provid[ing] women and men a means by which they decide for themselves the number, timing, and spacing of their children,” Cantwell Decl. ¶ 3, and Essential Access’s mission “to champion and promote quality sexual and reproductive health care for all,” Rabinovitz Decl. ¶ 3, are in accord. Both will be undermined by the Final Rule qualitatively and quantitatively.

First, the Final Rule will directly compromise providers’ ability to deliver effective care and force them to obstruct and delay patients with pressing medical needs. Abortion is a time-sensitive procedure; the medical risks and costs associated with it “increase with any delay.” Kost Decl. ¶ 93. Yet, the Final Rule erects barrier after barrier between patients trying to make an informed decision about whether to continue their pregnancies and their clinicians. A clinician *must* refer a pregnant patient to prenatal care that focuses on carrying the pregnancy to term, even if the patient has made clear her decision to terminate her pregnancy. *Id.* ¶¶ 87, 91. The clinician *cannot* refer the patient to a provider of abortion services, even if the patient specifically requests such a referral. *Id.* ¶ 88. At most the clinician may provide a referral list. Most of the list must be non-abortion providers—in other words, most of the list must be *non-responsive* to what the patient requests. *Id.* And the clinician is *barred* from even identifying to the patient which providers on the referral list are the ones she asked for (providers of abortion services), so the patient must expend further time and effort figuring out for herself which providers on the list in fact can give her the care she wants and needs. *Id.* Incredibly, the Final Rule does not require a clinician who furnishes a patient with a referral list that is wholly non-responsive to even *notify her that the list does not contain a single provider of the services she requested.* *Id.* This pregnancy counseling process is thus, as the President of Essential Access aptly puts it, a “charade” from beginning to end. Rabinovitz Decl. ¶ 50. The overall effect of the Final Rule is to “harm and confuse all patients” during a medically and emotionally sensitive period and “ultimately threaten their health and well-being.” Kost Decl. ¶¶ 90, 92, 94.

*9 *Second*, the Final Rule threatens to drastically reduce access to the wide array of services provided by Title X projects by driving large numbers of providers out of the program. Compliance with the physical separation requirement, which in many cases effectively requires

providers to establish “mirror” facilities and staff, would be cost-prohibitive for many providers in California’s Title X network. *See* Rabinovitz Decl. ¶ 43; Nestor Decl. ¶ 13; McKinney Decl. ¶ 10; Forer Decl. ¶ 31. In addition, a significant number of Title X projects have indicated that they will likely drop out of the program because they believe the Final Rule compels them to compromise the quality of care they provide and violate their ethical obligations. Sub-recipients of Essential Access’s Title X funds representing 233 clinic sites serving over 774,000 patients “would leave or consider leaving” Title X if they are prohibited from referring patients for abortion services. Rabinovitz Decl. ¶ 42. Sub-recipients representing 194 clinic sites serving over 682,000 patients “will leave or consider leaving” if they are required by the Final Rule to encourage family involvement where an adolescent patient seeks confidential services. *Id.*; *see, e.g.*, Nestor Decl. ¶¶ 11–12; McKinney Decl. ¶ 9. Likewise, “Planned Parenthood affiliates and their health centers”—which serve over 40% of all Title X patients nationwide—“would be forced to discontinue their participation in Title X if the Proposed Rule takes effect.” Rich Decl., Exh. M at 15–16.

The net effect of so many providers leaving Title X will be a significant reduction in the availability of important medical services. The substantial Title X funding Essential Access currently receives—approximately \$20 million per year—provides “comprehensive sexual and reproductive health care for more than 1 million” patients in California annually. Rabinovitz Decl. ¶¶ 1, 13–15. Essential Access has submitted evidence that the vast majority of its sub-recipients—85 percent—would be forced to lay off staff, cut training, and reduce outreach and education activities without that funding. *Id.* ¶ 44. A third would have to reduce clinic hours. *Id.* Some would have to shut down core services and programs entirely. *See, e.g.*, Thomas Decl. ¶¶ 11–13 (Fresno Economic Opportunities Commission “will not be able to operate” HEARTT, its family planning and reproductive health service for youth, without Title X funds); Nestor Decl. ¶¶ 5–10, 14 (Without Title X funds, the San Francisco Department of Public Health will have to “substantially curtail” its training programs, public education and outreach projects, and “special projects to address emerging public health challenges”); Marshall Decl. ¶ 28 (“Without Title X funding, CommuniCare will not run the outreach services that inform young people of its teen clinic services, nor provide teen clinic services at all.”); Wilburn Decl. ¶¶ 16–21, (“The loss of Title X funds will be nearly fatal to [the Community Action Partnership of San Luis Obispo County]’s Health and Prevention Division,” including its outreach programs, teen program, and [Hepatitis C](#) testing services).

If Title X funding is reduced, patients in California accordingly stand to lose access to a wide range of “vital health services,” many of which have nothing to do with abortion, since Title X providers “serve as a trusted entry point for medical care generally.” California Mot. at 24; *see, e.g.*, Rabinovitz Decl. ¶ 12 (“In 2017 alone, Essential Access sub-recipients ... provided more than 1.6 million family planning visits” and administered “more than 148,000 Pap tests, more than 118,000 clinical breast exams, more than 642,000 chlamydia screenings, more than 700,000 gonorrhea screenings, and more than 341,000 HIV tests.”); Brindis Decl. ¶¶ 59–60; Tuttle Decl. ¶ 8; McCarthy Decl. ¶ 7; Wilburn Decl. ¶¶ 17–19. In particular, “[i]n less populous regions, the Rule will create ‘contraceptive deserts’ where women in need of Title X-funded contraceptive services will be unable to find an affordable, well-qualified provider within their county.” California Mot. at 21. Nationwide, in one-fifth of U.S. counties the only safety-net family planning center is a Title X site. Kost Decl. ¶ 78. Should any of these sites drop out of the Title X program as a result of the Final Rule, many individuals would have no access to high-quality, affordable family planning care in their counties at all. *Id.* In California specifically, eighteen counties would be left without a single Title X-funded health center if all the family planning providers that perform abortions were to close. Rabinovitz Decl. ¶ 43.

*10 Even among providers who remain in Title X, service capacity will decrease because the requirement that pregnancy counseling can only be provided by physicians and APPs excludes “vast numbers of medical professionals” who currently provide such counseling. Rabinovitz Decl. ¶ 52; McKinney Decl. ¶ 11; Kost Decl. ¶ 86. This will compound an already “severe crisis in physician and nurse practitioner availability,” creating even more critical shortages in counseling resources. Castellano-Garcia Decl. ¶ 11. Many Title X grantees do not have enough physicians and APPs on staff to serve their patients, so those patients will have to either wait for much longer to receive counseling that is often time-sensitive, or simply will not receive the family-planning information they need. *See, e.g.*, McKinney Decl. ¶ 11; Forer Decl. ¶ 30.

Third, the quality of Title X services will be compromised. Patients served by Title X-funded providers use more effective contraceptive methods at higher rates than those served by non-Title X-funded providers. Rabinovitz Decl. ¶ 46. Title X patients “are more likely [than non-Title X patients] to adopt or continue using long-acting and reversible contraceptive methods (‘LARCs’),” which “are highly effective [in

preventing pregnancy] because they obviate the need for daily administration or use at the time of intercourse.” *Id.*, *see also* Kost Decl. ¶¶ 119–121 (describing a 35 percent reduction in women using LARCs after Texas “made a series of changes to its family planning program ..., which included disqualifying agencies providing abortion”). “Diminishing access to LARCs may result in a greater number of unintended pregnancies.” Rabinovitz Decl. ¶ 46. Moreover, the Final Rule’s separation provision requires health centers to maintain duplicate records systems. Such non-integrated records systems threaten patient health by increasing the risk of error due to “incomplete medical histories, missing data, lost test results, incorrect medication, dosage instructions, and allergy warnings, and other miscommunications across patient records.” *Id.* ¶ 70.

Ultimately, the consequence of the reduced availability and quality of health services is worse health outcomes for patients and the public as a whole. The number of unintended pregnancies will increase, which is “likely to result in premature births, low birth weight infants, and congenital defects.” Cantwell Decl. ¶¶ 24, 29; Brindis Decl. ¶¶ 52–55. Indeed, the Final Rule could have the perverse effect of *increasing* abortion rates, since “[o]ver half of unintended pregnancies end in miscarriage or abortion.” California Mot. at 23; Tosh Decl. ¶ 25 (citing report documenting that 45% of unintended pregnancies result in abortion, and another 13% result in miscarriages). Instances of STIs and other conditions that would otherwise be diagnosed by Title X-funded testing will also likely increase. *See* Brindis Decl. ¶¶ 59–65 (citing study estimating that in 2017, Title X-funded testing “averted approximately 90 to 400 cases of HIV and 47,740 to 56,670 other STIs,” diagnosed “many pelvic inflammatory disease (PID) cases, ectopic pregnancies, ... infertility cases” and “reproductive cancers”); Kost Decl. ¶ 82.

In short, there is substantial evidence in the record before the Court which establishes that California’s public health and Essential Access’s mission to promote quality sexual and reproductive care will be irreparably harmed unless the Final Rule is enjoined.

2. Economic Harm to California

Next, the economic harms that flow from the Final Rule’s detrimental effects on public health also constitute irreparable harm to California. *See California v. Health & Human Servs.*, 351 F. Supp. 3d 1267, 1297 (N.D. Cal. 2019) (“*HHS*”) (finding irreparable harm to plaintiff

states where HHS rule creating exemptions to the ACA contraceptive mandate will cause “tens of thousands of women” to lose contraceptive coverage, and the states “document[ed] the fiscal harm that will flow to them as a result”); *see also California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (“*Azar*”) (affirming finding of irreparable economic harm to states from the same HHS rules “because the states will not be able to recover monetary damages” for their APA claims per 5 U.S.C. § 702).

*11 California’s state Medicaid program, Medi-Cal, “is the primary funder for low-income Californians’ healthcare services.” Cantwell Decl. ¶ 28. Via Medi-Cal, the Final Rule’s impact on public health translates to substantial financial and administrative burdens for California. For example, Medi-Cal insures 64% of unplanned births in the state. Tosh Decl. ¶¶ 26, 44. It is estimated that each unintended pregnancy in California costs the public fisc \$6,557 in medical, welfare, and other social service costs. *Id.* ¶ 27. Moreover, Medi-Cal “would likely also bear a portion of the costs associated with any delays in the diagnosis and treatment of STIs or [breast or cervical cancer](#).” Cantwell Decl. ¶ 30.

3. Economic Harm to Essential Access

Essential Access will also suffer irreparable economic harm if the Final Rule’s physical separation requirement becomes effective. Because that requirement is so stringent, Essential Access estimates that it “will be forced to spend exorbitant sums to construct a ‘mirror’ office,” at the cost of \$325,000 in the first year and \$212,500 every year thereafter. Essential Reply at 13; Rabinovitz Decl. ¶ 66. Its sub-recipients estimate that compliance with the separation requirement will cost an average of \$119,000 per agency. Rabinovitz Decl. ¶ 69. Bringing its infrastructure into compliance with the separation requirement will also require Essential Access to divert resources it “otherwise devotes to its core operations and its mission.” Essential Mot. at 32 (citing Rabinovitz Decl. ¶ 67); *see E. Bay Sanctuary Covenant v. Trump*, 354 F. Supp. 3d 1094, 1116 (N.D. Cal. 2018) (holding that organizational plaintiffs “‘have established a likelihood of irreparable harm’ based on their showing of serious ‘ongoing harms to their organizational missions,’ including diversion of resources”) (quoting *Valle del Sol*, 732 F.3d at 1029). As with the economic harm to California, Essential Access’s economic harm is irreparable because it “will not be able to recover monetary damages” for its APA claims. *Azar*, 911 F.3d at 581 (citing 5 U.S.C. § 702)).

4. Defendants’ Responses to Plaintiffs’ Evidence of Irreparable Harm

Defendants attack Plaintiffs’ assertions of irreparable harm on several grounds.

First, Defendants do not dispute that damage to public health can constitute irreparable harm, but instead claim that the public health impact California is describing depends on the response of regulated third parties—*i.e.*, recipients of Title X funding—to the Final Rule, and therefore that the “chain of events necessary to create these speculative harms” is too “attenuated.” Opp. at 43 (citing *Lujan v. Defs. Of Wildlife*, 504 U.S. 555, 562 (1992)). Not so.

To begin with, Defendants ignore that the Final Rule’s harm to Title X patients described above directly undermines California’s public health objectives. Moreover, uncontroverted record evidence Plaintiffs have submitted shows that the harms they describe are not speculative; they are “*likely* in the absence of an injunction.” *Winter*, 555 U.S. at 22 (emphasis in original). As detailed above, Planned Parenthood has stated unequivocally that its whole network of health centers “would be forced to discontinue their participation in Title X if the Proposed Rule takes effect.” Rich Decl., Exh. M at 15. So have many Title X providers in California’s network. *See, e.g.*, Nestor Decl. ¶ 11; McKinney Decl. ¶ 9. Indeed, one has already dropped out of Title X as of April 4, 2019 in response to the Final Rule. *Essential Access* Docket No. 64 (Supplemental Rabinovitz Decl.) ¶ 5. Hundreds more have indicated that they “would leave or consider leaving” Title X if the Final Rule is implemented. Rabinovitz Decl. ¶ 42.

*12 Equally unambiguous are the adverse health consequences that will follow from the mass departure of Title X providers. The inverse correlation between the availability of publicly-funded contraceptives and the rate of unintended pregnancies is well-documented in the record. *See Brindis* Decl., Exh. B at 11, 12 n.73 (citing a 2015 report showing that 286,700 unintended pregnancies were averted in California in a single year as a result of publicly funded contraceptive services); Rich Decl., Exh. L at 31–32 (“Title X-funded services helped women avert an estimated 822,300 unintended pregnancies in 2015 alone, thus preventing 387,200 unplanned births and 277,800 abortions. Without services provided by these providers, the U.S. unintended pregnancy rate would have been 31% higher.”). Plaintiffs have also cited three case studies documenting the adverse health consequences that

directly resulted when family planning services providers that offer abortion-related services were excluded from public funding. *See* Brindis Decl., Exh. B at 6–7 (Indiana county that cut funding to Planned Parenthood facility almost immediately experienced “one of the largest and most rapid HIV outbreaks the country has ever seen”); Kost Decl. ¶¶ 119–22 (disqualifying agencies that provided abortion services from public funding in Texas and Iowa led to marked decreases in family planning services rendered and the use of effective contraceptives).

Moreover, there is already a “severe” shortage of physician and nurse practitioner availability, so implementation of the Final Rule’s physician and APP requirement will directly exacerbate patients’ lack of access to pregnancy counseling. Castellano-Garcia Decl. ¶ 11; McKinney Decl. ¶ 11; Forer Decl. ¶ 30. The resulting shortfall in service capacity caused would manifest immediately, before any final decision on the merits in this case will be reached. *See* 11A Charles Alan Wright et al., *Federal Practice and Procedure* § 2948.1 (3d ed. 2013) (“Perhaps the single most important prerequisite for the issuance of a preliminary injunction is a demonstration that if it is not granted the applicant is likely to suffer irreparable harm before a decision on the merits can be rendered.”). Nothing about this chain of causation is attenuated.

What *is* speculative is Defendants’ assurance that any gap left by an exodus in current Title X providers will be fully filled by new providers entering the program. Defendants point to HHS’s claim in the Final Rule that it “does not anticipate that there will be a decrease in the overall number of facilities offering [Title X] services, since it anticipates other, new entities will apply for funds, or seek to participate as subrecipients, as a result of the final rule.” 84 Fed. Reg. at 7782; *see also id.* at 7756. But this claim is not backed by any discernible evidence or analysis.⁴ *See* Part III.C.2.f., *infra* (discussing HHS’s analysis of the expected costs and benefits of the Final Rule). In fact, at oral argument, when pressed for any record evidence substantiating this (highly consequential) assertion, Defendants’ counsel could offer none. Counsel insisted that it is “just intuitive” that new grantees will fully replace departing ones in the “fluid marketplace” for medical services. Intuition is no rebuttal to Plaintiffs’ evidence of threatened irreparable harm. Nor is Defendants’ “intuition” presumed as a matter of logic and common sense. Plaintiffs note that nationwide, in one-fifth of U.S. counties, including rural counties in California, the only safety-net family planning center is a Title X site. Kost Decl. ¶ 78; *see also* Rabinovitz Decl. ¶ 51 (stating that in some rural areas of California, a patient would have to travel more than five hours in order to

access an abortion provider that qualifies for a referral under the Final Rule). It defies common sense to assume that in these regions, new healthcare centers will simply materialize and seamlessly assume the client load of exiting grantees.

Second, Defendants insist that the claimed harm to Essential Access is not imminent. Opp. at 43–44. This argument is unavailing for the same reason that the expected harm to California is not speculative—Plaintiffs’ evidence demonstrates that access to and the quality of family planning services will be adversely affected as soon as the Final Rule goes into effect. With respect to compliance costs, the process for establishing a physically and financially separate “mirror” office would “requir[e] Essential Access to expend resources on planning and implantation of operational changes *immediately* after the Final Rule takes effect.”⁵ Rabinovitz Decl. ¶ 66 (emphasis added); *see id.* ¶ 68. The same time pressure extends to Essential Access’s sub-recipients. McKinney Decl. ¶ 10. Furthermore, as to Essential Access’ ability to deliver quality health care, it cannot be ignored that abortion is a time-sensitive procedure, and the medical risks and costs associated with it “increase with any delay.” Kost Decl. ¶ 93; *cf. Chalk v. U.S. Dist. Court Cent. Dist. of California*, 840 F.2d 701, 710 (9th Cir. 1988) (finding that time-sensitive nature of AIDS diagnosis is a “factor favoring a preliminary injunction”). The Final Rule, by requiring Title X projects to provide incomplete and perhaps even misleading information to patients, and prohibiting projects from referring patients to abortion providers, forces patients to expend more time and effort to secure information and referrals regarding abortions. In doing so, it increases the health risks and limits the care options for pregnant women, whether they have already decided to obtain an abortion or are simply seeking more information to guide their determination of whether to continue their pregnancies. *See* Kost Decl. ¶ 94 (“[T]he inability to make a fully informed decision on how to proceed with a pregnancy would be especially harmful for women with severe *diabetes*, heart conditions, HIV/AIDS and estrogen-dependent tumors—all conditions that could be exacerbated by continuing a pregnancy.”). In other words, the Final Rule is likely to jeopardizing patients’ welfare as soon as it is implemented, thus impairing both patient health and Essential Access’ central mission.

*13 *Third*, Defendants argue that the alleged harm to Essential Access’s sub-recipients and Title X patients is not harm to Essential Access itself. *See* Opp. at 43. This argument misses the point. As noted above, Essential Access’s organizational mission is to “promote quality sexual and reproductive health care for all.” Rabinovitz Decl. ¶ 3. It works toward this mission in part by

distributing Title X funds to its sub-recipients to facilitate their provision of family planning services to patients. *Id.* ¶ 6. Thus, the potentially detrimental impact the Final Rule will have on those sub-recipients' capacities to provide services to Title X patients is just one manifestation of the harm that Essential Access will suffer with respect to its organizational mission.

Fourth, Defendants recite the proposition that "ordinary compliance costs are typically insufficient to constitute irreparable harm." Opp. at 45 (quoting *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005)). "But as the Ninth Circuit recently reiterated, the general rule that '[e]conomic harm is not normally considered irreparable' does not apply where there is no adequate remedy to recover those damages, such as in APA cases." *E. Bay Sanctuary Covenant*, 354 F. Supp. 3d at 1116 (quoting *Azar*, 911 F.3d at 581). In *East Bay Sanctuary*, the court found that the plaintiffs established a likelihood of irreparable harm "based on their showing of serious 'ongoing harms to their organizational missions,' including diversion of resources and the non-speculative loss of substantial funding from other sources." 354 F. Supp. 3d at 1116 (citing *Valle del Sol*, 732 F.3d at 1029). The same reasoning obtains here, because Essential Access and its sub-recipients will not be able to recover for the substantial costs they would need to expend to come into compliance with the new separation requirements even if the Final Rule is found to violate the APA.

Accordingly, Plaintiffs have satisfied the irreparable harm prong of the preliminary injunction inquiry.

B. The Balance of Equities and the Public Interest

Where the government is a party to a case in which a preliminary injunction is sought, the balance of the equities and public interest factors merge. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). Here, both factors weigh in favor of preliminarily enjoining the Final Rule.

On Plaintiffs' side is their interest in averting the "potentially dire public health and fiscal consequences from the implementation of the Final Rules," *HHS*, 351 F. Supp. 3d at 1298, discussed above. The Final Rule threatens to impair the health and welfare of women who benefit from Title X-funded services and Plaintiffs' mission to provide quality healthcare. Moreover, there are the "substantial costs stemming from a higher rate of unintended pregnancies that are likely to occur if women

lose access to the [family planning] coverage afforded under the rules now in place." *Id.* And Plaintiffs are not the only ones that will suffer hardship absent an injunction. See *Golden Gate Rest. Ass'n v. City & Cty. of San Francisco*, 512 F.3d 1112, 1126 (9th Cir. 2008) ("In considering the public interest, we may consider the hardship to all individuals covered by the [challenged law], not limited to parties"). As explained above, public health problems will adversely impact the general public. See *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1139 (9th Cir. 2009) ("The 'general public has an interest in the health' of state residents.") (quoting *Golden Gate Rest. Ass'n*, 512 F.3d at 1126). A group of thirteen municipalities has also submitted an amicus brief explaining that they will be harmed by the Final Rule in analogous ways to California by the implementation of the Final Rule. See *Essential Access* Docket No. 62 at 7–13. Each of these municipalities receives substantial Title X funding annually and they collectively serve hundreds of thousands of patients through their Title X programs. See *id.* at 4–7.

*14 On the other hand, Defendants identify no substantiated harm if a preliminary injunction were to issue. They have not documented any substantial abuse of Title X funds. See Part III.C.2.b., *infra*. The only harm Defendants currently assert is that which the government will suffer "if it 'is enjoined by a court from effectuating statutes enacted by representatives of its people.'" Opp. at 46 (quoting *Maryland v. King*, 567 U.S. 1301 (2012) (Roberts, C.J., in chambers)). But as Judge Gilliam pointed out in another case: "Here, of course, the 'representatives of the people'—the United States Congress—passed the [relevant statute], and the precise question in this case is whether the Executive's attempt to implement the Final Rules is inconsistent with Congress's directives." *HHS*, 351 F. Supp. 3d at 1299. As set forth in detail below, this Court finds a high likelihood that the Final Rule was promulgated in violation of substantive statutory law and APA-mandated procedures, and "[t]here is generally no public interest in the perpetuation of unlawful agency action." *League of Women Voters of United States v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) (citations omitted). "To the contrary, there is a substantial public interest 'in having governmental agencies abide by the federal laws that govern their existence and operations.'" *Id.* (quoting *Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994)). It may be true that Defendants intend the Final Rule to represent the government's "value judgment favoring childbirth over abortion," Opp. at 46 (quoting *Rust*, 500 U.S. at 192–93), but that value judgment cannot be effectuated in an unlawful manner or in violation of other Congressional directives.

Hence, the balance of hardships and the public interest tip sharply in favor of Plaintiffs. Although injunctive relief is thus warranted “if [Plaintiffs] can only show that there are ‘serious questions going to the merits,’ ” *All. for the Wild Rockies*, 865 F.3d at 1217, for the reasons discussed below, Plaintiffs have done more than show “serious questions.” They have established they are likely to succeed on the merits of many of their claims.

C. Likelihood of Success on the Merits/Serious Questions Going to the Merits

California argues that it is likely to succeed on its APA claims because the Final Rule is not in accordance with law and exceeds statutory authority, in violation of 5 U.S.C. § 706(2)(A) and (2)(C). California also contends the Rule is arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A).⁶ California Mot. at 10–19. Essential Access makes similar arguments under the APA, as well as an additional contention that the Final Rule was promulgated without proper notice and comment. Essential Mot. at 9–21. It also presses two constitutional claims: that the Final Rule infringes upon Dr. Marshall’s First Amendment rights, and that it is void for vagueness under the Fifth Amendment Due Process Clause. *Id.* at 21–25. Each claim is addressed below.

1. The Final Rule is Not in Accordance with Law

The APA requires a reviewing court to “hold unlawful and set aside agency action” that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). “ ‘[N]ot in accordance with law’ ... means, of course, *any* law, and not merely those laws that the agency itself is charged with administering.” *F.C.C. v. NextWave Pers. Commc’ns Inc.*, 537 U.S. 293, 300 (2003) (emphasis in original). Defendants assert that the Final Rule cannot be unlawful under § 706(2)(A) because it is “materially indistinguishable from [the 1988 rule] the Supreme Court has already upheld” in *Rust*. Opp. at 8. Plaintiffs, however, rely on HHS Appropriations Acts and the ACA, which were enacted after *Rust* was decided, so their claim is not automatically foreclosed by *Rust*. The Court therefore must determine whether the Final Rule is inconsistent with the Appropriations Acts and the ACA.

a. The Nondirective Counseling Provision

The most recent “Department of Defense and Labor, Health and Human Services, and Education Appropriations Act” provides:

For carrying out the program under title X of the PHS Act to provide for voluntary family planning projects, \$286,479,000: *Provided*, That amounts provided to said projects under such title shall not be expended for abortions, *that all pregnancy counseling shall be nondirective*, and that such amounts shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.

*15 Pub. L. No. 115-245, Div. B, Tit. II, 132 Stat 2981, 3070–71 (2018) (emphasis added). This “Nondirective Counseling Provision” has been included in HHS appropriations acts (“Appropriations Acts”) every year since 1996 in substantially similar form. *See, e.g.*, Omnibus Consolidated Rescissions and Appropriations Act of 1996, Pub. L. No. 104-134, 110 Stat. 1321, 1321–22 (1996) (requiring that “all pregnancy counseling shall be nondirective”).

According to Plaintiffs, the provisions of the Final Rule that restrict abortion counseling and referral conflict with the Nondirective Counseling Provision. *See* California Mot. at 11–12; Essential Mot. at 13–14. Defendants in their briefing initially took this to mean that Plaintiffs were arguing that “the nondirective provision implicitly repealed section 1008 and *Rust*,” Opp. at 14, because *Rust* upheld similar provisions in the 1988 regulations as a permissible construction of Section 1008. However, Defendants subsequently recognized that the doctrine of implied repeal is not apposite here because the Nondirective Counseling Provision and Section 1008 are not in irreconcilable conflict. *See Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 154–55 (1976) (explaining that

repeals by implication come into play “where provisions in the two acts are in irreconcilable conflict”) (citation omitted); Opp. at 16 (“There is no conflict—much less an irreconcilable one—between Title X ... and the nondirective provision.”). *Rust* did not purport to interpret Section 1008 as requiring directive counseling in favor of birth; rather, it held that HHS’s 1988 rule was one permissible interpretation, not the only permissible interpretation. See *Rust*, 500 U.S. at 184 (“The language of § 1008—that ‘[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning’—does not speak directly to the issues of counseling, referral, advocacy, or program integrity.”). Indeed, at oral argument, Defendants’ counsel agreed with Plaintiffs that Section 1008 and the Nondirective Counseling Provision can be read in harmony—requiring pregnancy counseling under Title X to be nondirective does not necessarily run afoul of Section 1008’s general proscription that no Title X funds “shall be used in programs where abortion is a method of family planning.” That is demonstrated by HHS’s 2000 regulations, which proscribed funding of abortions but permitted nondirective pregnancy counseling.⁷

The question is whether the Final Rule, as one interpretation of Section 1008, is inconsistent with the Appropriations Acts’ mandate that “pregnancy counseling” be “nondirective.” HHS does not dispute that it has an obligation to comply with the Nondirective Counseling Provision. It wrote in the notice of proposed rulemaking for the Final Rule that “[s]ince it originally created the Title X program in 1970, Congress has, from time to time, imposed additional requirements on it,” including “the annual Title X appropriation includes the provisos that ‘all pregnancy counseling shall be nondirective.’ ” 83 Fed. Reg. 25502, 25502 (2018) (“Proposed Rule”); *id.* at 25507 n.11 (“That counseling on abortion be nondirective is required by the appropriations law applicable to Title X.”). Similarly, the Final Rule states that Title X “projects *must* comply with Congress’s requirement that pregnancy counseling be nondirective, and the Department *must* enforce that requirement.” 84 Fed. Reg. at 7747 (emphases added).

*16 As Defendants see it, however, the Final Rule is not inconsistent with the Nondirective Counseling Provision because § 59.14(b)(1) of the Final Rule allows a Title X provider to “choose to provide ... [n]ondirective pregnancy counseling” to a pregnant patient. Plaintiffs contend, on the other hand, that the Final Rule is inconsistent with the Nondirective Counseling Provision because it mandates referrals to prenatal care while categorically barring referrals for “abortion as a method of family planning,” and imposes unreasonable

restrictions on the provision of referral lists for patients seeking an abortion. Plaintiffs also argue that even without the referral prohibition and restrictions, the Final Rule “effectively prohibits nondirective counseling ... by issuing a vague prohibition on providers who ‘encourage’ or ‘promote’ abortion.” California Mot. at 11. Plaintiffs believe this “unclear guidance will likely cause providers to forgo discussions altogether for fear of violating the Rule.” *Id.* at 12.

i. “Nondirective Counseling” Includes Referrals

The first part of the parties’ dispute focuses on whether “nondirective counseling” under the Appropriations Acts encompasses referrals. It does, as indicated by statute, regulations, and industry practice. First, Congress expressed its understanding in the PHSA that “nondirective counseling” includes referral. See 42 U.S.C. § 254c-6(a)(1)⁸ (providing that HHS shall make training grants “providing adoption information *and referrals* to pregnant women on an equal basis with all other courses of action *included in nondirective counseling* to pregnant women”) (emphases added). The PHSA and the HHS Appropriations Acts appear to be the only instances in which Congress has used the term “nondirective counseling,” and Defendants have not argued otherwise. Notably, the Final Rule, in interpreting Title X, incorporates the definition of “nondirective counseling” from § 254c-6(a)(1) of the PHSA in the context of adoption. 84 Fed. Reg. at 7733 (“Congress has expressed its intent that postconception adoption information and *referrals be included as part of any nondirective counseling* in Title X projects when it passed [§ 254c-6(a)(1)].”) (emphasis added). Congress’ use of the identical term “nondirective counseling” should be read consistently across the PHSA and the HHS Appropriations Acts to include referrals as part of counseling. See *Dir., OWCP v. Newport News Shipbldg. & Dry Dock Co.*, 514 U.S. 122, 130 (1995) (teaching that, in interpreting an ambiguous statutory phrase, “[i]t is particularly illuminating to compare” two different statutes employing the “virtually identical” phrase); *cf. Erlenbaugh v. United States*, 409 U.S. 239, 243 (1972) (“[A] legislative body generally uses a particular word with a consistent meaning in a given context.”).

Second, as a matter of regulatory law, HHS itself characterizes referrals as part of counseling throughout the Final Rule. See *id.* at 7730 (“[N]ondirective pregnancy counseling can include counseling on adoption, and

corresponding referrals to adoption agencies.”); 7733–34 (“Title X providers may provide adoption counseling, information, and referral as a voluntary family planning service for non-pregnant clients ... as part of nondirective postconception counseling”). The Final Rule, in this regard, is not unique. As early as 1981, HHS has defined counseling in its Title X Guidelines to include referral. See U.S. Dep’t of Health and Human Services, *Program Guidelines for Project Grants for Family Planning Services* § 8.2 (1981) (“Post-examination counseling should be provided to assure that the client ... receives appropriate referral for additional services as needed.”) (emphases added).

Third, the accepted usage within the medical field of “nondirective counseling” supports Plaintiffs’ position. See *Louisiana Pub. Serv. Comm’n v. F.C.C.*, 476 U.S. 355, 357 (1986) (articulating “the rule of construction that technical terms of art should be interpreted by reference to the trade or industry to which they apply”) (citing *Corning Glass Works v. Brennan*, 417 U.S. 188, 201–02 (1974)); *Alabama Power Co. v. EPA*, 40 F.3d 450, 454 (D.C. Cir. 1994) (“[W]here Congress has used technical words or terms of art, it is proper to explain them by referring to the art or science to which they are appropriate.”). This is reflected in the HHS Office of Population Affairs’ (“OPA”) own “Quality Family Planning” guidelines (“QFP Guidelines”), which are incorporated into the agency’s Title X Family Planning Guidelines.⁹ See Center for Disease Control and Prevention, *Providing Quality Family Planning Services* (2014), <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>; Rich Decl., Exh. A at 5. The “Pregnancy Testing and Counseling” section of the QFP Guidelines instructs that “[p]regnancy test results should be presented to the client, followed by a discussion of options and appropriate referrals.”¹⁰ Brindis Decl., Exh. C at 13–14. The QFP Guidelines then advise that “[o]ptions counseling should be provided in accordance with recommendations from professional medical associations, such as ACOG [the American College of Obstetricians and Gynecologists] and AAP [the American Academy of Pediatrics].” *Id.* at 14. “Both ACOG and AAP are explicit in their recommendations that all pregnant individuals, including adolescents, be provided with factual, nondirective pregnancy options counseling that includes information on and timely referral for abortion services.” Kost Decl. ¶ 25. The American Medical Association’s comment letter to the Proposed Rule likewise states unequivocally that “[t]he inability to counsel patients about all of their options in the event of a pregnancy and to provide any and all appropriate referrals, including for abortion services, are contrary to the AMA’s Code of Medical Ethics.” Rich Decl., Exh. I at 3. See also Rabinovitz Decl.

¶ 33 (“Nondirective counseling ... requires nondirective referrals for particular services—including abortion—upon request of the patient.”).

*17 That Congress intended “nondirective counseling” include nondirective “referrals” is reinforced by the fact that Congress repeatedly enacted the Nondirective Counseling Provision in substantially the same form every year since 1996. Throughout these last 23 years the HHS regulations have consistently interpreted Title X to “require[], in the event of an unplanned pregnancy and where the patient requests such action, [grantees] to provide nondirective counseling to the patient on all options relating to her pregnancy, including abortion, and to refer her for abortion, if that is the option she selects.” 58 Fed. Reg. at 7464. “Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change.” *Lorillard v. Pons*, 434 U.S. 575, 580 (1978) (citations omitted); see *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1154–55 (9th Cir. 2010).

Defendants counter by relying on general dictionary definitions to urge that “[c]ounseling” does not, in its common usage, necessarily include within its definition the act of ‘referral.’ ” Opp. at 17 (quoting Black’s Law Dictionary (10th ed. 2014)). But the Court need not resort to indications of common usage because there is ample statutory, regulatory, and industry guidance on the meaning of “counseling” in the specific context of medical services at issue here. See *United States v. Lettiere*, 640 F.3d 1271, 1274 (9th Cir. 2011) (“Only in the absence of a statutory definition does this court normally look to the ordinary meaning or dictionary definition of a term.”); see also *United States v. Costello*, 666 F.3d 1040, 1044 (7th Cir. 2012) (cautioning that “[d]ictionary definitions are acontextual, whereas the meaning of sentences depends critically on context, including all sorts of background understandings”).

Next, Defendants point to various instances in the Final Rule where the phrase “counseling and referral” is used. See, e.g., 84 Fed. Reg. at 7730 (“[T]he Department believes that Title X providers can provide certain counseling and referrals in a postconception setting”), 7747 (“Nondirective counseling and referrals for postconception services ... are the appropriate approach in the context of pregnancy”), 7778 (“[T]he final rule eliminates the requirement that Title X projects provide abortion counseling and referral.”). To Defendants, the conjunction “and” indicates that counseling and referral are discrete activities. Absent any other interpretive guidance, this may be a plausible reading. But given the express references to counseling as “including” referral in

the PHSA, elsewhere in HHS regulations, and in the Final Rules, the phrase “counseling and referral” occasionally used by HHS is more sensibly read as simply describing sequential aspects of the same process.

Finally, Defendants cite a 1992 bill that expressly sought to “reverse[] the regulations issued in 1988 and upheld by the Supreme Court in 1991 to restrict the provision of information on abortion to Title-Ten patients.” Opp. at 17 (quoting [H.R. Rep. No. 102-204, at 1](#) (1991)). The bill, which was passed by Congress but vetoed by President George H. W. Bush, defined “pregnancy management options” to mean “nondirective counseling and referrals.” S. 323, 102nd Cong. § 2 (1992). Defendants contend that Congress’ later enactment of the Nondirective Counseling Provision *without* specific mention of “referral” as in the 1992 bill signifies that Congress intended to exclude referral from the scope of nondirective counseling mandated by the subsequent Appropriations Acts. See Opp. at 18. This argument ignores important context. The 1992 bill was introduced in the immediate wake of and as an explicit response to the *Rust* decision. Because *Rust* upheld the 1988 regulations that expressly banned abortion counseling and referrals, it is not surprising that Congress felt the need to specify in explicit terms that it was putting both abortion-related counseling and referral back on the table. But by the time Congress enacted the Nondirective Counseling Provision in 1996, the pre-1988 regulatory scheme that treated abortion referrals as a part of counseling had already been restored. See [58 Fed. Reg. 7462](#). Since 1993, the HHS regulations have permitted abortion referrals. This obviated the need for the Nondirective Counseling Provision to make explicit reference to both counseling and referral.

*18 Although Defendants invoke the proposition that “[f]ew principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language,” [United States v. Novak, 476 F.3d 1041, 1071 \(9th Cir. 2007\)](#), it is hazardous to apply this principle to divine the intent of a Congress that passed the Nondirective Counseling Provision four years after the vetoed 1992 bill given the different historical contexts of the 1992 bill and the subsequent 1996 Appropriations Act. See [Cohen v. United States, 650 F.3d 717, 730 \(D.C. Cir. 2011\)](#) (“[I]t is the enacted text rather than the unenacted legislative history that prevails.”) (citation omitted). Defendants cite nothing in the legislative history suggesting that Congress in 1996 considered, and rejected, a version of the Nondirective Counseling Provision that expressly required abortion referral or that Congress otherwise intended to exclude referrals from the provision.

In sum, the Court finds that the statutory language, PHSA, Title X regulations, and usage within the medical field all indicate that nondirective counseling includes nondirective referrals.

ii. The Final Rule’s Referral Restrictions Violate the Nondirective Counseling Provision

Applying this definition, sections 59.14(a), 59.14(b)(1), and 59.14(c)(2) of the Final Rule likely violate the Nondirective Counseling Provision. “Nondirective pregnancy counseling is the meaningful presentation of options where the [medical professional] is not suggesting or advising one option over another.” [84 Fed. Reg. at 7716](#); see [42 U.S.C. § 254c-6\(a\)\(1\)](#) (providing that nondirective pregnancy counseling involves “providing adoption information and referrals to pregnant women on an equal basis with all other courses of action”). To be nondirective, the medical professional must “present[] the options in a factual, objective, and unbiased manner and ... rather than present[] the options in a subjective or coercive manner.” [84 Fed. Reg. at 7747](#).

The categorical prohibition on providing referrals for abortion in § 59.14(a) is not nondirective because it prevents Title X projects from presenting abortion on an equal basis with other pregnancy options.¹¹ In contrast to § 59.14(a), § 59.14(b)(1) mandates that every pregnant patient be referred to “prenatal health care,” even a patient who has expressly stated that she does not want prenatal care. This differential treatment is not “nondirective.” The mandate compels providers to present the options in a coercive manner and pushes patients to pursue one option over another; it does not allow “clients [to] take an active role in processing their experiences and identifying the direction of the interaction.” [84 Fed. Reg. at 7716](#). Indeed, Defendants conceded at oral argument that if referral is considered a part of counseling, § 59.14(b)(1) violates the Nondirective Counseling Provision.

Defendants also acknowledged that the referral list restrictions in § 59.14(c)(2) stand and fall together with the prohibition on abortion referrals in § 59.14(a). Section 59.14(c)(2) allows Title X projects to provide a client with a referral list “limited to those that do not provide abortion,” even if the client specifically requests an abortion referral. It further prevents projects from providing a referral list on which “the majority” of the providers perform abortion services, and from

“identify[ing] which providers on the list perform abortion.” Far from meaningfully presenting a patient with her medical options, such a “non-referral referral list” (as Plaintiffs’ counsel labels it) is likely to cause confusion and delay in her attempt to obtain care. The patient would have to spend time working through the list to determine which referrals actually provide the services she asked for—time she may not have given the time-sensitive nature of decisions about pregnancy and related care. Imposing these onerous restrictions only on abortion information does not place abortion on an equal basis with all other courses of action.

iii. The Final Rule’s Counseling Restrictions Violate the Nondirective Counseling Provision Apart From Referrals

*19 There is also merit to Plaintiffs’ contention that, the referral prohibition aside, the Final Rule one-sidedly chills counseling regarding abortion. Sections 59.5(a)(5) and 59.14(a) bar providers from doing anything to “promote” or “support” abortion. See also § 59.16(a)(1) (“A Title X project may not encourage, promote or advocate abortion as a method of family planning.”). At oral argument, Defendants’ counsel struggled to draw a clear boundary between mentioning or describing abortion as a pregnancy option within the permissible scope of nondirective counseling and “promoting” or “supporting” abortion impermissible under §§ 59.5(a)(5) and 59.14(a). Essentially, counsel was only able to offer a circular definition: A provider can avoid “promoting” or “supporting” abortion by counseling nondirectively, and a provider can counsel nondirectively by not “promoting” or “supporting” abortion. This interpretive murkiness is telling. It suggests that providers desiring to explain the abortion option have to walk on eggshells to avoid a potential transgression of the Final Rule, whereas those describing the option of continuing the pregnancy face no comparable risk. This lack of symmetry created by §§ 59.5(a)(5) and 59.14(a) is likely to chill discussions of abortion and thus inhibits neutral and unbiased counseling.

Accordingly, Plaintiffs have established a likelihood of success on the merits of their claim that sections 59.14(a), 59.14(b)(1), and 59.14(c)(2) violate the Nondirective Counseling Provision of the Appropriations Acts and are thus not in accordance with law.

b. Section 1554 of the ACA

Plaintiffs next argue that the Final Rule violates Section 1554 of the ACA. See California Mot. at 12–13; Essential Mot. at 10–13. Section 1554 provides:

Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—

- (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
- (2) impedes timely access to health care services;
- (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
- (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
- (5) violates the principles of informed consent and the ethical standards of health care professionals; or
- (6) limits the availability of health care treatment for the full duration of a patient’s medical needs.

42 U.S.C. § 18114.

i. Defendants’ Threshold Arguments Do Not Foreclose Plaintiffs’ Section 1554 Claim

Before proceedings to the merits of Plaintiffs’ Section 1554 claim, the Court first addresses several threshold issues raised by Defendants.

(a) Plaintiffs’ Section 1554 Claim Has Not Been Waived

First, Defendants argue that Plaintiffs have waived any challenge based on Section 1554 because they did not raise the issue with HHS during the notice and comment period. Opp. at 19. It is a “general rule” that courts “will not review challenges to agency action raised for the first time on appeal.” *Portland Gen. Elec. Co. v. Bonneville Power Admin.*, 501 F.3d 1009, 1023 (9th Cir. 2007)

(citing *Exxon Mobil Corp. v. E.P.A.*, 217 F.3d 1246, 1249 (9th Cir. 2000)). Parties may thus “waive[] their right to judicial review” of arguments “not made before the administrative agency” or “in the comment to the proposed rule.” *Exxon Mobil*, 217 F.3d at 1249. Plaintiffs concede that neither they nor any other commenter specifically notified HHS during the comment period that the Proposed Rule may violate Section 1554. However, they assert that numerous commenters stated that the Final Rule violated the ACA, and therefore that HHS was “provided sufficient notice ... to afford it the opportunity to rectify the [Section 1554] violations that the plaintiffs alleged.” *Native Ecosystems v. Dombeck*, 304 F.3d 886, 899 (9th Cir. 2002). Plaintiffs compiled these comments in a supplemental submission to the Court. See *California* Docket No. 97.

In reviewing whether these comments are sufficient to overcome waiver, the Court heeds the Ninth Circuit’s guidance that “the exhaustion requirement should be interpreted broadly.” *Nat’l Parks & Conservation Ass’n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1065 (9th Cir. 2010). “Plaintiffs need not state their claims in precise legal terms, and need only raise an issue ‘with sufficient clarity to allow the decision maker to understand and rule on the issue raised.’ ” *Id.* (quoting *Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 968 (9th Cir. 2006)).

*20 Applying this permissive standard, the Court finds that, although it is a close call, Plaintiffs have raised at least a serious question as to whether their Section 1554 claim has been adequately exhausted. The record suggests that commenters raised issues pertaining to Section 1554 with sufficient clarity to provide notice to HHS. Several comments specifically contend the Final Rule violates the ACA. See, e.g., *California* Docket No. 97 ¶ 2 (“The proposed definition of what would be considered a ‘medically approved’ family planning method ... would effectively limit access and coverage of reproductive health choices expanded upon in the ACA ...”), ¶ 4 (This proposed change is ... contrary to the Affordable Care Act ...”).

In themselves, these comments may not be specific enough to suggest that the Final Rule violates any specific provision of the ACA. But they were complemented by numerous comments using identical or substantially identical language to Section 1554 to describe how the Final Rule would impede access to care. Compare, e.g., § 1554(1) (“... creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care”), with *California* Docket No. 97 ¶ 6 (“The Proposed Rule seeks to create barriers to access to women’s healthcare, including abortion.”) and ¶ 7 (The Proposed Rule “would

create barriers to access for an even larger number of women nationwide.”); § 1554(2) (“... impedes timely access to health care services”), with *California* Docket No. 97 ¶ 14 (The Proposed Rule “would prevent Title X providers from sharing complete and accurate medical information necessary to ensure that their patients are able to ... obtain timely care.”) and ¶ 17 (“This proposed gag on providers will prevent patients from accessing health care in a timely manner.”); § 1554(3) (“... interferes with communications regarding a full range of treatment options between the patient and the provider”), with *California* Docket No. 97 ¶ 20 (“The NPRM would ban Title X providers from giving women full information about their health care options.”) and ¶ 22 (“The proposed rule limits how Title X providers can discuss and/or counsel on the full-range of sexual and reproductive health care options with their patients.”); § 1554(4) (“... restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions”), with *California* Docket No. 97 ¶ 25 (The Final Rule “undermines the right to information by censoring health care providers from informing patients of all their options related to abortion.”).

The comments raising concerns regarding medical ethics and informed consent per § 1554(5) are particularly specific. Compare § 1554(5) (“... violates the principles of informed consent and the ethical standards of health care professionals”), with *California* Docket No. 97 ¶ 26 (“The Proposed Rule requires physicians to disregard their Code of Medical Ethics ...”), ¶ 27 (“The Proposed Rule directly conflicts with the recommendations of major medical professional associations, including the American College of Obstetricians and Gynecologists and the American College of Physicians ...”), ¶ 31 (“[T]he rule’s proposed ban on abortion referral and its chilling effect (or possibly an effective ban) on abortion counseling are repudiations of ethical and professional standards around informed consent ...”). The terms “ethical standards” and “informed consent” are commonly understood within the medical field to refer to established standards, including those published by the American College of Physicians (“ACP”) and the American College of Obstetricians and Gynecologists (“ACOG”). HHS has long referenced these ethical standards in connection with Title X, including throughout its QFP Guidelines. See, e.g., QFP Guidelines at 13; 65 Fed. Reg. at 41273–74.

*21 To be sure, these comments did not explicitly reference Section 1554, but the Ninth Circuit has repeatedly emphasized that commenters “need not state their claims in precise legal terms” to exhaust them, *Nat’l Parks*, 606 F.3d at 1065, and “alerting the agency in general terms will be enough if the agency has been given

a chance to bring its expertise to bear to resolve the claim,” *Lands Council v. McNair*, 629 F.3d 1070, 1076 (9th Cir. 2010) (citation and alteration omitted). *See, e.g., Oregon Nat. Desert Ass’n v. McDaniel*, 751 F. Supp. 2d 1151, 1165 (D. Or. 2011) (finding no waiver where plaintiff raised the issue underlying its Wilderness Act claim by complaining to the agency that its action would harm “500,000 acres of recommended future wilderness,” “even though it never actually invoked the Wilderness Act before the agency”); *Sierra Forest Legacy v. U.S. Forest Serv.*, 652 F. Supp. 2d 1065, 1081 (N.D. Cal. 2009). And here, HHS acknowledged that it had received many comments objecting that the Final Rule created barriers to patients’ access to care, interfered with provider-patient communications, and violated principles of medical ethics, and addressed them (albeit unsatisfactorily, *see* Part III.C.2., *infra*). *See, e.g., 84 Fed. Reg. at 7722–24, 7745* (acknowledging comments regarding barriers to access to care and medical ethics).

That HHS dismissed the concerns raised in these comments, which were couched in the same terms as Section 1554’s prohibitions, indicates that the commenters “raise[d] [the] issue with sufficient clarity to allow the decision maker to understand and rule on the issue raised,” *Nat’l Parks*, 606 F.3d at 1065, and that the agency’s response would likely have been no different even if the commenters had specifically cited Section 1554.¹² *See Native Ecosystems*, 304 F.3d at 899 (holding that where “the administrative decisionmaker understood plaintiffs to raise the issue” and “addressed this concern in its decision,” there is no waiver); *Nat. Res. Def. Council v. E.P.A.*, 755 F.3d 1010, 1023 (D.C. Cir. 2014) (holding that an issue “expressly addressed by” the agency “is properly before the court”).

Accordingly, the Court concludes that Plaintiffs have raised a serious question that their Section 1554 claim was not waived.

(b) Section 1554 Limits the Secretary’s Authority under Title X

Second, Defendants argue that Section 1554 does not affect the scope of HHS’s rulemaking authority under Title X. Defendants reason that the prefatory language in Section 1554, “[n]otwithstanding any other provision of this Act,” limits the scope of Section 1554 to the ACA. 42 U.S.C. § 18114. According to Defendants, if Congress had intended for Section 1554 to sweep more broadly

beyond the ACA, it could have written the statute to say, “notwithstanding any other provision of law.” *Opp.* at 21–22.

However, the plain text of Section 1554 does not limit its application to the ACA. “Notwithstanding any other provision of this Act” simply means that the Secretary cannot engage in the type of rulemaking proscribed by Section 1554 even if another provision of the ACA could be construed to permit it—the directive of Section 1554 is to be given primacy. This meaning is underscored by the expansive second clause of Section 1554: “the Secretary of Health and Human Services shall not promulgate *any regulation*” 42 U.S.C. § 18114 (emphasis added). The literal text of Section 1554 does not support Defendants’ construction.

That Section 1554 has application beyond the ACA is neither surprising nor unusual; surrounding provisions do too. *See, e.g., 42 U.S.C. § 18116(a)* (nondiscrimination provision that extends to all federally-funded health programs). Moreover, where Congress wanted a provision to apply only to the ACA, it said so explicitly. For example, Section 1553 directs that “[t]he Federal Government, and any State or local government or health care provider that *receives Federal financial assistance under this Act* ... may not subject an individual or institutional health care entity to discrimination” 42 U.S.C. § 18113(a) (emphasis added). Similarly, Section 1555 provides that “[n]o individual, company, business, nonprofit entity, or health insurance issuer offering group or individual health insurance coverage shall be required to participate in any Federal health insurance program *created under this Act*.” 42 U.S.C. § 18115 (emphasis added). The “clear” and “express” language in these sections limiting their applicability to the ACA demonstrates that “Congress knows how to limit the [statute] when it wishes to do so.” *Miller v. Clinton*, 687 F.3d 1332, 1340 (D.C. Cir. 2012). Congress did not use such express language in Section 1554.

*22 Defendants invoke two other principles of statutory interpretation to argue that Section 1554 does not apply to Title X. Neither advances Defendants’ cause. The first is the “principle that Congress ‘does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions.’ ” *Opp.* at 20 (quoting *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 468 (2001)). In Defendants’ telling, it is implausible that Congress would have “abrogated a Supreme Court decision on an *extremely* controversial subject”—*Rust*—by means of an ancillary ACA provision. *Id.* (emphasis in original). But this account is fundamentally flawed because when the ACA was enacted in 2010, the counseling and referral

restrictions in *Rust* had long been rescinded, so Section 1554 was entirely consistent with the prevailing Title X regulatory scheme. And as noted above, *Rust* merely upheld one interpretation of Title X; it did not purport to definitively interpret Title X itself. Thus, Section 1554, to the extent it bars the “gag rule,” would not abrogate Section 1008.

The second principle is that “the specific [statute] governs the general.” Opp. at 22 (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992)). Defendants assert that Section 1008, as a specific prohibition on funding abortion as a method of family planning within Title X, trumps the more general Section 1554. See *id.* at 23. This “canon is impotent, however, unless the compared statutes are ‘irreconcilably conflicting.’ ” *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 698–99 (D.C. Cir. 2014) (citation omitted). For the reasons just discussed, Section 1008 and Section 1554 are not irreconcilably conflicting. And Defendants recognize as much. See Opp. at 21. The former forbids the use of Title X funds “in programs where abortion is a method of family planning,” 42 U.S.C. § 300a-6, whereas the latter limits HHS’s authority to promulgate any regulation which violates the principles of informed consent and ethical standards of medical professionals, *id.* § 18114. These “two statutes are capable of co-existence.” *Morton*, 417 U.S. at 551. The pre-Final Rule regulatory scheme gives effect to both. It prevents impermissible use of Title X funds by enforcing financial separation between projects that receive Title X funding and projects that perform services prohibited under Section 1008. At the same time, it permits Title X projects to give patients nondirective counseling and referrals to abortion service providers upon request, in compliance with Section 1554(5).

Because there is no “irreconcilable conflict” between the two statutes, Defendants’ contention that Plaintiffs’ claim relies on the premise that Section 1554 impliedly repealed Section 1008 is likewise inapposite. See Opp. at 20; *Radzanower*, 426 U.S. at 154–55 (one statute can be found to have impliedly repealed another “where provisions in the two acts are in irreconcilable conflict”).

(c) Section 1554 is Not Unreviewably Broad

Third, Defendants suggest that Section 1554 is so “open-ended” that “it is a substantial question whether section 1554 claims are reviewable under the APA at all.” Opp. at

22. Defendants cite *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971) for the proposition that there are times when “statutes are drawn in such broad terms that in a given case there is no law to apply,” frustrating judicial review. *Id.* at 410. But *Overton Park* made clear that this is “a very narrow exception” to the APA only to be applied in “rare instances.” *Id.* This is not one of those rare instances. Other, arguably more open-ended statutory commands have been held to permit judicial review. See, e.g., *Morgan Stanley Capital Group Inc. v. Pub. Util. Dist. No. 1 of Snohomish County*, 554 U.S. 527, (2008) (wholesale electricity rates must be “just and reasonable”); *Pac. Nw. Generating Co-op. v. Bonneville Power Admin.*, 596 F.3d 1065, 1077 (9th Cir. 2010) (agency must operate “consistent with sound business principles”); *City of Los Angeles v. U.S. Dep’t. of Commerce*, 307 F.3d 859, 869 n.6 (9th Cir. 2002) (Secretary of Commerce must use statistical sampling “if he considers it feasible”); *Keating v. FAA*, 610 F.2d 611, 612 (9th Cir. 1979) (agency must make decision “in the public interest”). Section 1554 is not a statute “drawn so that the court would have no meaningful standard against which to judge the agency’s exercise of discretion.” *Heckler v. Chaney*, 470 U.S. 821, 830 (1985).

(d) The Constitutional Reasoning in *Rust* Does Not Foreclose Plaintiffs’ Section 1554 Claim

*23 Finally, Defendants, citing reasoning from *Rust*, made a further suggestion at oral argument that Plaintiffs’ Section 1554 claim is meritless because, even if the Final Rule impeded patients’ access to care, “[t]he difficulty that a woman encounters when a Title X project does not provide abortion counseling or referral leaves her in no different position than she would have been if the Government had not enacted Title X.” *Rust*, 500 U.S. at 202. This belated challenge is both legally and factually misguided.

As a legal matter, Defendants are importing language from *Rust*’s constitutional holding in an attempt to extinguish Plaintiffs’ statutory claim. The *Rust* Court decided that the 1988 regulations did not impermissibly burden a woman’s Fifth Amendment right to choose whether to terminate her pregnancy because “Congress’ refusal to fund abortion counseling and advocacy leaves a pregnant woman with the same choices as if the Government had chosen not to fund family-planning services at all.” *Id.* It was in this context of evaluating a constitutional claim that the Court reasoned the

regulations left patients no worse off than if Title X did not exist. *See id.* By contrast, Plaintiffs' claim here is that the Final Rule violates a specific statutory prohibition. The statutory mandates of Section 1554 are far more specific than the constitutional requirement asserted in *Rust*. The claim under Section 1554 is a matter of statutory interpretation to which *Rust* is inapposite.

Moreover, as a factual matter, the Final Rule's referral list restrictions go far beyond anything in the 1988 regulations. The new restrictions: (1) permit a Title X project to give a patient who *specifically requests* a referral for abortion a referral list that contains *no* abortion providers; (2) require the project to compile a list of providers, a majority of whom are *not* responsive to the patient's request; (3) prevents the project from identifying which providers on the list *are* responsive to the patient's needs; and (4) *does not require the project to even alert the patient that the list is incomplete and non-responsive*. *See* § 59.14(c)(2). Because of these provisions, patients in need of time-sensitive medical care will be delayed or altogether prevented from obtaining that care because they will receive referrals that they do not realize are not for the services they requested. *See* Rich Decl., Exh. K at 2. In other words, under the Final Rule, the Government would be subsidizing the misdirection of unsuspecting patients. Unlike in *Rust*, the Final Rule may well make patients *worse* off than if they had not sought help from a Title X project to begin with.¹³

ii. The Final Rule Violates Section 1554

Having found that Plaintiffs' claim under Section 1554 is not foreclosed, the Court must determine whether the Final Rule in fact violates that provision of the ACA. Plaintiffs assert that the Final Rule's restrictions on counseling and referral and requirement for providers to encourage family participation in family planning decisions are contrary to Section 1554. The Court agrees.

*24 The Court has already detailed extensively the ways in which the Final Rule's overlapping restrictions on pregnancy counseling (including referral and referral lists) obfuscate and obstruct patients from receiving information and treatment for their pressing medical needs. *See* Parts III.A.1 and III.C.1.a., *supra*; Kost Decl. ¶¶ 88–93; Rabinovitz Decl. ¶ 50; Marshall Decl. ¶ 22. There is no question that these restrictions “create[] ... unreasonable barriers to the ability of individuals to obtain appropriate medical care,” “impede[] timely

access to health care services,” “interfere[] with communications regarding a full range of treatment options between the patient and the provider,” and “restrict[] the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions” in violation of subparts (1)–(4) of Section 1554. Defendants do not even contest this.

Separately, the Final Rule's prohibition on providing abortion referrals, restrictions on the content of referral lists, and mandate on referrals for prenatal care are also squarely at odds with established ethical standards and therefore Section 1554(5). Indeed, they are inconsistent with HHS's own QFP Guidelines, which provide that once a patient receives a positive pregnancy test:

Referral to appropriate providers of follow-up care should be made at the request of the client, as needed. Every effort should be made to expedite and follow through on all referrals. For example, providers might provide a resource listing or directory of providers to help the client identify options for care. Depending upon a client's needs, the provider may make an appointment for the client, or call the referral site to let them know the client was referred.

QFP Guidelines at 14. The QFP Guidelines further instruct that “[p]roviders of family planning services should offer pregnancy testing and counseling services as part of core family planning services, in accordance with recommendations of major professional medical organizations, such as the American College of Obstetricians and Gynecologists (ACOG).” *Id.* at 13. In turn, ACOG explains that physicians have an ethical obligation to “provide a pregnant woman who may be ambivalent about her pregnancy full information about all options in a balanced manner, including raising the child herself, placing the child for adoption, and abortion.” Rich Decl., Exh. G at 6.

Clearly, the Final Rule's blanket prohibition on abortion referrals does not comport with providers' ethical obligation to provide “[r]eferral to appropriate providers of follow-up care ... at the request of the client.” QFP Guidelines at 14. And § 59.14(c)(2)'s restrictions that

prevent Title X from providing any abortion referrals to a patient who specifically requests such a referral, and from identifying which providers on a referral list perform abortion services, do not “help the client identify options for care.” *Id.* Comments in the record show that associations of medical professionals overwhelmingly agree that the Final Rule’s counseling and referral restrictions violate principles of medical ethics and informed consent. *See, e.g.*, Rich Decl., Exh. B at 4–5 (California Medical Association stating that restrictions “directly conflict[] with the requirements of medical professional associations, including [ACOG].”); Exh. D at 4 (American Academy of Nursing stating that restrictions “violate[] basic ethics of the profession,” including the Code of Ethics for Nurses); Exh. E at 7 (Guttmacher Institute stating that restrictions “constitute[] an unacceptable repudiation of the doctrine of informed consent by denying Title X patients factual, unbiased information on abortion”); Exh. G at 3–6 (ACOG stating that restrictions violate its Code of Professional Ethics); Exh. I at 3 (American Medical Association stating restrictions “are contrary to the AMA’s Code of Medical Ethics”); Exh. K at 2 (American Public Health Association stating that “[t]he gag rule violates core ethical standards”); Exh. N at 3 (American Academy of Pediatrics stating that restrictions “conflict[] with medical practice guidelines, including those of the American Academy of Pediatrics.”); Exh. P at 4–5 (American College of Physicians stating that restrictions violate “the ethical principle of respect for patient autonomy”); *see also* Marshall Decl. ¶ 15; Spirtos Decl. ¶ 18; Kost Decl. ¶¶ 84–85.

***25** The requirement in § 59.14(b)(1) that all pregnant Title X clients “shall be referred to a health care provider for medically necessary prenatal health care,” even if it goes against a patient’s wishes, violates ethical standards. As ACOG explains, this provision “require[s] the provision of counseling, information, and referral for services that the patient has clearly stated she does not wish to receive.” Rich Decl., Exh. G at 3, 6.

Moreover, as the American Public Health Association details, § 59.14(b)(1) also violates ethical principles because while it allows Title X providers to abstain from providing nondirective counseling due to moral or religious reasons, “it does not contain any requirement that those providers advise patients of their refusal.” Rich Decl., Exh. K at 2. “Therefore, patients will not even know if they are getting complete information.” *Id.*

Finally, the Final Rule’s “family participation” requirement also violates ethical standards. Title X itself only asks grantees to “encourage family participation” in

Title X projects “[t]o the extent practical.” 42 U.S.C. § 300(a). But Section 59.5(a)(14) directs Title X grantees to “[e]ncourage family participation in the decision to seek family planning services; and, with respect to each minor patient, ensure that the records maintained document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).” There is an exception to the documentation requirement where a provider “suspects the minor to be the victim of child abuse or incest.” § 59.2(1)(i). The American Academy of Pediatrics (“AAP”) notes that healthcare professionals already “highly encourage[] the involvement of families in the care of adolescents and young adults as much as possible,” and “[a]s a consequence, most adolescents already involve their families in decisions about family planning.” Rich Decl., Exh. N at 6. However, the new requirement in the Final Rule for “clinicians to take ‘specific actions’ to encourage family participation, even after they have learned that this involvement is not practicable,” is “contrary to medical ethics.” *Id.* AAP explains that “clinicians sometimes learn of circumstances (short of abuse) in a minor’s family that make it not ‘practicable,’ or unrealistic or even harmful to encourage the minor to involve their parents or guardian.” *Id.* In these situations, requiring clinicians to nevertheless encourage family participation and document those efforts would both force them to breach their ethical obligations and “drive some minors away from returning for critical health services.”¹⁴ *Id.* Other commenters, including ACOG, echo AAP’s conclusion that § 59.5(a)(14) violates medical ethics. *See id.*, Exh. G at 14.

***26** Accordingly, Plaintiffs have demonstrated that they are likely to succeed on the merits of their claim that §§ 59.5(a)(5), 59.5(a)(14), 59.14(a), 59.14(b)(1), 59.14(c)(2), and 59.16(a)(1) of the Final Rule are not in accordance with Section 1554.

2. The Promulgation of the Final Rule was Arbitrary and Capricious

Under the APA, agency action must be set aside if it is arbitrary or capricious. 5 U.S.C. § 706(2)(A). An agency must “examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Although “a court is not to substitute its judgment for that of the agency,” *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009) (citation omitted), it nevertheless “retain[s] a role,

and an important one, in ensuring that agencies have engaged in reasoned decisionmaking.” *Judulang v. Holder*, 565 U.S. 42, 53 (2011).

In particular, an agency which changes its position must give a reasoned explanation for the change. “[T]he requirement that an agency provide reasoned explanation for its action would ordinarily demand that [an agency] display awareness that it *is* changing position.” *Fox Television*, 556 U.S. at 515 (emphasis in original). Typically, the agency “need not demonstrate to a court’s satisfaction that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better.” *Id.* (emphases in original). “This means that the agency need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate.” *Id.* But “[s]ometimes it must—when, for example, its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account.” *Id.* at 515–16. Indeed, “even when reversing a policy after an election, an agency may not simply discard prior factual findings without a reasoned explanation.” *Organized Vill. of Kake v. U.S. Dep’t of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015).

“Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *State Farm*, 463 U.S. at 43.

a. Plaintiffs’ Arbitrary and Capricious Claims are Not Foreclosed by *Rust*

Defendants contend Plaintiffs’ arbitrary and capricious claims are foreclosed by *Rust*. See Opp. at 24–26. This argument is meritless. When it decided *Rust* in 1991, the Supreme Court found that “the Secretary amply justified his change of interpretation [from the pre-1988 regulations] with a ‘reasoned analysis,’ ” based on “critical reports of the General Accounting Office (GAO) and the Office of the Inspector General (OIG), that prior policy failed to implement properly the statute.” *Rust*, 500 U.S. at 187. “He also determined that the new regulations

are more in keeping with the original intent of the statute, are justified by client experience under the prior policy, and are supported by a shift in attitude against the ‘elimination of unborn children by abortion.’ ” *Id.*

*27 The justifications supporting the 1988 regulations upheld in *Rust* cannot insulate the Final Rule from review now, almost three decades later. In promulgating the Final Rule, HHS did not purport to rely on the 1988 regulations. See *Michigan v. E.P.A.*, 135 S. Ct. 2699, 2710 (2015) (It is a “foundational principle of administrative law that a court may uphold agency action only on the grounds that the agency invoked when it took the action.” Nor can HHS rely *ipse dixit* on the factual bases justifying the 1988 regulations. See *Sierra Club v. U.S. E.P.A.*, 671 F.3d 955, 966 (9th Cir. 2012) (“[An agency] stands on shaky legal ground relying on significantly outdated data” to justify its actions.). Unlike the 1988 regulations considered in *Rust*, the Final Rule was not enacted in response to critical reports of the GAO and OIG, and makes no mention of negative “client experiences” under the current regulations that have been in effect since 1993. Nor does the Final Rule cite any instances of actual comingling or misuse of Title X funds. Accordingly, that *Rust* upheld the 1988 regulations does not dispose of Plaintiffs’ APA challenge to the Final Rule here. This Court must conduct the arbitrary and capricious analysis anew.

As another threshold issue, Defendants contended at oral argument that Plaintiffs’ arbitrary and capricious claims are foreclosed by the *Chevron* analysis in *Rust*. According to Defendants, the mere fact that the 1988 regulations were a permissible interpretation of Title X alone supplies the reasoned basis HHS needs to justify the Final Rule under the APA. This argument is belied by *Rust* itself. If a reasonable and permissible statutory interpretation was all that was needed for the 1988 regulations to pass muster under arbitrary and capricious review, the Supreme Court would have said so. Although the ambiguous language of Section 1008 and equivalent legislative history of Title X might arguably have sustained the 1988 regulations, as noted above, the Court nevertheless scrutinized the evidentiary basis given for the 1988 regulations to ensure that they were the product of a “reasoned analysis.” *Rust*, 500 U.S. at 187.

On this point, Defendants overlook important differences between *Chevron* and arbitrary-and-capricious review. As the Ninth Circuit has delineated, “*Chevron* ... analyzes the reasonableness of an agency’s interpretation [of a statute], while ‘arbitrary and capricious’ review under the APA focuses on the reasonableness of an agency’s decision-making processes.” *CHW W. Bay v. Thompson*, 246 F.3d

1218, 1223 (9th Cir. 2001) (emphasis in original) (citation omitted). Here, it is precisely the reasonableness of HHS’s decisionmaking process in promulgating the Final Rule that Plaintiffs challenge. Hence, the lens of arbitrary-and-capricious review must be applied. See *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016) (“[W]here a proper challenge is raised to the agency procedures, and those procedures are defective, a court should not accord *Chevron* deference to the agency interpretation.”); *New York Public Interest Research Group v. Whitman*, 321 F.3d 316, 324 (2d Cir. 2003) (“When the question is not one of the agency’s authority but of the reasonableness of its actions, the ‘arbitrary and capricious’ standard of the APA governs.”). It would be particularly inappropriate to conflate *Chevron* and *State Farm* in this case because, as detailed below, Plaintiffs have persuasively shown that the Final Rule “was issued without the reasoned explanation that was required in light of [HHS]’s change in position and the significant reliance interests involved.” *Encino Motorcars*, 136 S. Ct. at 2126.

Accordingly, the Court proceeds to the merits of Plaintiffs’ arbitrary and capricious claims to determine whether the Final Rule is supported generally by a reasoned analysis, and in particular to the extent the Final Rule represents a change in position which requires a “more detailed justification,” whether HHS sufficiently justified its change in position.

b. The Physical Separation Requirement is Arbitrary and Capricious

*28 Plaintiffs contend the physical separation requirement in § 59.15 is arbitrary and capricious. See California Mot. at 17; Essential Mot. at 15–17. The record reveals that Plaintiffs are likely correct. HHS relied on speculative fears of theoretical abuse of Title X funds to justify imposing the physical separation requirement and turned a blind eye to voluminous evidence documenting the significant adverse impact the requirement would have on the Title X network and patient health. The agency’s actions fell short of reasoned decisionmaking.

i. Defendants Relied on Speculative Justifications Belied

by the Record

The Final Rule cites the following justification for requiring physical separation:

[S]hared facilities create a risk of the intentional or unintentional use of Title X funds for impermissible purposes, the co-mingling of Title X funds, the appearance and perception that Title X funds being used in a given program may also be supporting that program’s abortion activities, and the use of Title X funds to develop infrastructure that is used for the abortion activities of Title X clinics. Even with the strictest accounting and charging of expenses, a shared facility greatly increases the risk of confusion and the likelihood that a violation of the Title X prohibition will occur.

84 Fed. Reg. at 7764. Defendants’ opposition brief affirms that the physical separation requirement is based on “the need for prophylactic measures to address the risk and the perception that taxpayer funds will be used to fund abortion.” Opp. at 30.

Defendants’ repeated use of words like “risk,” “likelihood,” “prophylactic,” and “specter” is telling; Defendants fail to point to any evidence in the record of *actual* co-mingling or misuse of Title X funds. HHS primarily relies on two sources to justify its concerns about insufficient separation. The first is an “anecdotal story” from 2007 about a California clinic’s community outreach activities. 84 Fed. Reg. at 7774. But this anecdote, by Defendants’ own admission, does not actually involve the misuse of Title X funds at all. It is an “example of abuse of federal funds in a *different* program,” Medicaid. Opp. at 29 n.3 (emphasis added); see 84 Fed. Reg. at 7725 (“The Department agrees with comments stating that demonstrated abuses of Medicaid funds do not necessarily mean Title X grants are being abused”). The second is a 2014 Guttmacher Institute report indicating that “abortions are increasingly performed at sites that focus primarily on contraceptive and family planning services—sites that could be recipients of Title X funds.” 84 Fed. Reg. at 7765. But this report provides no support for HHS’s position. By the

agency's own interpretation, the report merely shows that abortions are being performed at "sites that *could* be recipients of Title X funds," *id.* (emphasis added); it does not say that those sites actually *are* Title X projects. Even assuming that abortions are being performed at actual Title X sites, there is no basis for concluding that this would constitute a violation of Title X. It is important here to remember the Supreme Court's explanation in *Rust* that

Title X expressly distinguishes between a Title X *grantee* and a Title X *project*. The grantee, which normally is a health-care organization, may receive funds from a variety of sources for a variety of purposes. The grantee receives Title X funds, however, for the specific and limited purpose of establishing and operating a Title X project.... The Title X *grantee* can continue to perform abortions, provide abortion-related services, and engage in abortion advocacy; it simply is required to conduct those activities through programs that are separate and independent from the project that receives Title X funds.

*29 500 U.S. at 196 (emphases in original) (citing 42 U.S.C. § 300(a)). Thus, the mere fact that abortions are being performed at the site of a Title X *grantee* does not mean that the Title X *project* operating within the grantee is misusing Title X funds to perform abortions. HHS cites no evidence to contradict its prior finding that financial separation and the concomitant review and rigorous audit of Title X grantees' financial records was a sufficient safeguard. See 65 Fed. Reg. at 41275–76.¹⁵

The evidence HHS cites for its concern about public "perception that Title X funds being used" in relation with prohibited abortion activities, 84 Fed. Reg. at 7764, is equally without a reasoned basis. According to the agency, in response to the Proposed Rule, it received comments from "many commenters that oppose defining 'family planning' to exclude abortion and that urge the Department to define the term to include abortion." *Id.* at 7729. Far from showing that the public erroneously believes Title X funds are being used to fund abortion-related activities, these comments suggest the very

opposite—that the commenters understand Title X funds *cannot* currently be used for abortion, but would like HHS to change its definition of "family planning" to include abortion so that Title X funds *can* potentially be used for abortion-related activities.

Defendants advance another argument: they believe that "the collocation of a Title X clinic with an abortion clinic permits the abortion clinic to achieve economies of scale" and therefore "support[s] abortion as a method of family planning" with Title X funds. *Id.* at 7766. But the notion that any use of Title X funds that might indirectly benefit an abortion clinic is necessarily misuse is a radical one that goes far beyond any rationale for physical separation approved in *Rust*. It ignores a pivotal distinction drawn in *Rust*: "Title X expressly distinguishes between a Title X *grantee* and a Title X *project*," and a "Title X *grantee* can continue to ... provide abortion-related services" so long as it does so "through programs that are separate and independent from the project that receives Title X funds." 500 U.S. at 196 (emphases in original). HHS's sweeping new argument would obliterate the Court's carefully drawn distinction. The limitless reach of the agency's rationale is also "illogical on its own terms." *Am. Fed'n of Gov't Emps., Local 2924 v. Fed. Labor Relations Auth.*, 470 F.3d 375, 380 (D.C. Cir. 2006). A grantee that, pursuant to the Final Rule, maintains separate facilities and medical records between its Title X services and abortion services can still benefit from economies of scale in, for example, rent (if the grantee rents separate spaces within the same building) and medical record system (if the grantee purchases its separate systems from the same vendor). See *id.* (an agency's decision is arbitrary and capricious if "illogical on its own terms"); *Illinois Pub. Telecom. Ass'n v. F.C.C.*, 117 F.3d 555, 566 (D.C. Cir.) (an agency's "seemingly illogical" decision is arbitrary and capricious), *decision clarified on reh'g*, 123 F.3d 693 (D.C. Cir. 1997).

In sum, the asserted fear of misuse of Title X funds purporting to animate HHS's decision to fundamentally depart from its current regulations and impose an onerous physical separation requirement are not substantiated by the record. To the contrary, HHS reported as recently as October 2018 that "family planning projects that receive Title X funds are closely monitored to ensure that federal funds are used appropriately and that funds are not used for prohibited activities, such as abortion." Angela Napili, *Congressional Research Service Report for Congress: Family Planning Program Under Title X of the Public Health Service Act*, at 14 (Oct. 15, 2018), <https://fas.org/sgp/crs/misc/R45181.pdf>.

*30 Defendants contend they do not need to justify the

Final Rule by reference to an extant problem, because “agencies can ... adopt prophylactic rules to prevent potential problems before they arise.” *Stilwell v. Office of Thrift Supervision*, 569 F.3d 514, 519 (D.C. Cir. 2009) (Kavanaugh, J.). However, “[t]hrough an agency’s predictive judgments about the likely economic effects of a rule are entitled to deference, deference to such judgments must be based on some logic and evidence, not sheer speculation.” *Sorenson Commc’ns Inc. v. F.C.C.*, 755 F.3d 702, 708 (D.C. Cir. 2014) (citations, internal quotation marks and alterations omitted). In *Sorenson Communications*, the D.C. Circuit found arbitrary and capricious a rule providing that the Federal Communications Commission (“FCC”) would only reimburse service providers for captioning-enabled phones they sold to hearing-impaired individuals if those phones cost \$75 or more. *Id.* at 705. The FCC “claim[ed] the \$75 Rule w[ould] deter fraudulent acquisition and use of [captioning-enabled phones]. Yet the agency offer[ed] no evidence suggesting there is fraud to deter.” *Id.* at 707. The court faulted the FCC for promulgating the rule without an evidentiary basis, asking, “where is the evidence that [the] technology is being fraudulently used?” *Id.* at 708. The court rejected the FCC’s assertion “that it may rely on its predictive judgment to ignore these questions” and concluded that the agency had “failed to articulate a satisfactory explanation for its action” because its claimed fear of fraud was speculative. *Id.* at 708–09; see also *Nat’l Fuel Gas Supply Corp. v. F.E.R.C.*, 468 F.3d 831, 839 (D.C. Cir. 2006) (finding that agency action premised on addressing “a claimed record of abuse” is arbitrary and capricious because the agency “provided no evidence of a real problem” with abuse); *Arizona Cattle Growers’ Ass’n v. U.S. Fish & Wildlife, Bureau of Land Mgmt.*, 273 F.3d 1229, 1244 (9th Cir. 2001) (holding agency action to be arbitrary and capricious where the basis of the action is “speculation ... not supported by the record.”).

Likewise here, HHS purports to rely on its predictive judgment that Title X funds will be misused without the physical separation requirement, but the Final Rule provides no evidence that indicates this projection is anything but speculation. Quite the opposite, the projection is at odds with the agency’s repeated assurances from as early as 2000 and as recently as 2018 that the existing separation requirements are sufficient to prevent abuse within the Title X program. Accordingly, HHS has failed to “articulate a satisfactory explanation” for the physical separation requirement as required by the APA, and is thus arbitrary and capricious. *State Farm*, 463 U.S. at 43.

ii. HHS Failed to Provide a “More Detailed Justification” for Its Change in Policy

The arbitrary nature of the change in policy becomes even more clear when HHS’s decisionmaking is measured against its obligation to supply “a more detailed justification” for adding the physical separation requirement; a detailed justification is required because its decision relied “upon factual findings that contradict those which underlay its prior policy” and because “its prior policy has engendered serious reliance interests.” *Fox Television*, 556 U.S. at 515.

HHS clearly set forth the factual findings underlying its decision in 2000 to rescind the physical separation requirement in the 1988 regulations. It noted, on the one hand, that mandating physical separation conferred no discernible benefits. The agency reasoned that it had “traditionally viewed” financial separation—“demonstrate[d] by [a Title X grantee’s] financial records, counseling and service protocols, administrative procedures, and other means”—as sufficient. 65 Fed. Reg. at 41276. And “since Title X grantees are subject to rigorous financial audits, it can be determined whether program funds have been spent on permissible family planning services, without additional requirements being necessary.” *Id.* at 41275. Thus, “it is hard to see what additional statutory protection is afforded by the imposition of a requirement for ‘physical’ separation.” *Id.* at 41276. On the other hand, HHS concluded that a physical separation requirement “is not likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services.” *Id.* The agency took seriously comments objecting that physical separation would be “costly[] and medically unwise.” *Id.* at 41275. In particular, requiring separation of staff and facilities would: “be inefficient and cost ineffective,” especially “for small and rural clinics that may be the only accessible Title X family planning and/or abortion providers for a large population of low-income women”; be “inconsistent with public health principles, which recommend integrated health care”; and “burden women, by making them make multiple appointments or trips to visit different staff or facilities.” *Id.* at 41275–76 (internal quotation marks omitted).

*31 By contrast, in reinstating the physical separation requirement in the Final Rule, HHS stated that “it no longer believes financial separation is sufficient without physical separation.” 84 Fed. Reg. at 7764. It also

“disagree[d]” with commenters who protested “that the physical and financial separation requirements will destabilize the network of Title X providers” by imposing significant compliance costs. *Id.* at 7766. Instead, the agency “believes that, overall, the final rule will contribute to more clients being served, gaps in services being closed, and improved client care that better focuses on the family planning mission of the Title X program.” *Id.* These factual findings upon which the Final Rule rests “contradict those which underlay [HHS’s] prior policy.” *Fox Television*, 556 U.S. at 515.

The prior separation policy also engendered “serious reliance interests” with respect to regulated entities, including Plaintiffs. Essential Access has detailed the significant investment it has made in its physical infrastructure, programming, and records systems over the years in reliance on the longstanding rule that financial separation between its Title X and non-Title X activities complies with Section 1008. For example, core to Essential Access’s mission of promoting quality reproductive care is its training arm, the Learning Exchange, which “trained more than 6,000 clinicians and allied health professionals from forty-nine states on providing quality sexual and reproductive health care” in 2017. Rabinovitz Decl. ¶ 61. Based on the current regulations, the Learning Exchange programming includes “training on pregnancy options, including how to provide patients with medically accurate, unbiased, non-judgmental information about abortion, adoption, and parenting.” *Id.* ¶ 62. Similarly, Essential Access provides “extensive” non-Title X-funded public education and awareness programming, reaching over 650,000 adolescents, about comprehensive sexual and reproductive health. *Id.* ¶ 64. The Final Rule would require Essential Access to completely overhaul this programming and reallocate its resources in order to comply with the new requirement that any activities relating to abortion must be conducted “with a separate staff, under a separate roof, using separate workstations, email addresses, and phone numbers.” *Id.* ¶ 65. This entails “extraordinary expenses.” *Id.* ¶ 66.

Essential Access sub-recipients likewise would need to revamp their “medical record systems and financial records, undertake extensive renovations, and hire new staff and personnel,” which are integrated in reliance on the current regulations. *Id.* ¶ 69. See also Nestor Decl. ¶¶ 5–6, 13 (San Francisco Department of Public Health uses Title X funds to train its clinical staff members on “contraceptive counseling” and “pregnancy testing and counseling,” but it “cannot bear the cost of setting up separate facilities” and “separate personnel” to bifurcate its Title X and non-Title X services); Forer Decl. ¶¶ 7, 31

(Title X grantee Venice Family Clinic provides “fully integrated primary healthcare services,” including family planning services, and it would be “financially impossible for [its] three Title X funded clinic sites to build entirely separate adjoining sites”); McKinney Decl. ¶¶ 8, 10 (Title X grantee Westside Family Health Center, which does not provide abortions but does “provide nondirective pregnancy counseling and referrals for abortion when requested,” cannot afford to “rent or purchase separate property to provide non-directive counseling or referrals for abortion services”). As Plaintiffs’ counsel explained at oral argument, these investments made in integrated staff and systems mean that a reversal of course by the agency now would engender more costs than would have been incurred if the separation requirement had been in force years ago.

*32 The reliance interests these Title X grantees have demonstrated are similar to those recognized by the Supreme Court as warranting a more detailed explanation of an agency’s change in policy. See *Encino Motorcars*, 136 S. Ct. at 2126–27 (holding that automobile dealerships had established “decades of industry reliance” on prior Department of Labor policy exempting dealerships from paying overtime compensation to “service advisors,” because “[d]ealerships and service advisors negotiated and structured their compensation plans against this background understanding,” and eliminating the exemption “could necessitate systemic, significant changes to the dealerships’ compensation arrangements”). Defendants attempt to distinguish *Encino Motorcars* on the basis that it “concerned private parties’ substantive statutory rights,” where “the challenged regulations here concern discretionary funding decisions” and grants that are “generally available for only one year.” Opp. at 31. But courts have recognized serious reliance interests in discretionary grants of benefits that do not arise from statute—in, for example, the Deferred Action for Childhood Arrivals program, a form of time-limited discretionary relief from deportation created by an executive branch memorandum. See *Regents of Univ. of California v. United States Dep’t of Homeland Sec.*, 279 F. Supp. 3d 1011, 1022, 1045 (N.D. Cal.), *aff’d sub nom. Regents of the Univ. of California v. U.S. Dep’t of Homeland Sec.*, 908 F.3d 476 (9th Cir. 2018); *Nat’l Ass’n for the Advancement of Colored People v. Trump*, 315 F. Supp. 3d 457, 473 (D.D.C. 2018); *Batalla Vidal v. Nielsen*, 279 F. Supp. 3d 401, 431 (E.D.N.Y. 2018). To the extent Defendants suggest that any reliance on the current Title X regulations was unreasonable because agency policy can change at any time, that argument ignores the fact that the type of review described in *Fox Television* was specifically made in the context of a change in an agency’s policy, not a statute. As the Court

in *Fox Television* explained, one purpose of arbitrary-and-capricious review of agency action is precisely to safeguard reliance interests from being upended by erratic policy shifts by administrative agencies. See 556 U.S. at 515. Here, Title X grantees have relied on HHS consistently interpreting Section 1008 to require only financial separation for over a quarter century; that the Supreme Court required a more detailed explanation from an agency changing a policy that had engendered “decades of industry reliance” reflects that regulated entities are justified in structuring their affairs in reliance on longstanding agency policy. *Encino Motorcars*, 136 S. Ct. at 2126.

At bottom, HHS has not demonstrated there are “good reasons” for the physical separation requirement or provided a “more detailed justification” for the change in policy. *Id.*

iii. HHS Failed to Provide Any Explanation for Its Estimates of Compliance Costs

The promulgation of the physical separation requirement is arbitrary and capricious for a second, independent reason. During the notice-and-comment period, commenters provided HHS with substantial evidence that imposing a physical separation requirement on Title X grantees would create significant (and in many cases, prohibitive) compliance costs, drastically reduce access to Title X services, and lead to serious disruptions in care for Title X patients. Instead of engaging with these concerns, HHS summarily dismissed them, maintaining that “overall, the final rule will contribute to more clients being served, gaps in services being closed, and improved client care that better focuses on the family planning mission of the Title X program.” 84 Fed. Reg. at 7766. In doing so, the agency “entirely failed to consider an important aspect of the problem” and “offered an explanation for its decision that runs counter to the evidence before the agency.” *State Farm*, 463 U.S. at 43.

With respect to compliance costs, HHS’s analysis at every stage of the rulemaking has been mystifying. Initially, the Proposed Rule “estimate[d] that an average of between \$10,000 and \$30,000, with a central estimate of \$20,000, would be incurred [by each affected Title X site] to come into compliance with physical separation requirements in the first year following publication of a final rule.” 83 Fed. Reg. at 25525. In reaching these figures, the agency quoted several costs grantees are likely to incur to

“evaluate[] ... whether they comply with the proposed physical separation requirements.” *Id.* But merely *evaluating* the compliance status of a Title X site is only the first of many steps in the process of actually *coming into compliance* with the physical separation requirement. For instance, sites will need to maintain separate accounting and health records, as well as separate physical facilities (including “treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites.”) § 59.15(a)–(c). There is no mention of the costs of complying with these requirements in the Proposed Rule.¹⁶ Also conspicuously absent is any estimate of compliance costs beyond the first year.

*33 Many Title X grantees submitted detailed comments explaining that their compliance costs would be much higher than estimated in the Proposed Rule. Planned Parenthood estimated that just the capital costs of renovation and construction would be “nearly \$625,000 per affected service site.” Rich Decl., Exh. M at 31–32 (providing extensive calculations). The National Family Planning and Reproductive Health Association wrote that “[i]t would cost hundreds of thousands of dollars or more to locate and open a facility, staff it, purchase separate workstations, set up separate record-keeping systems, etc.,” and estimated capital costs of compliance at \$300,000. *Id.*, Exh. L at 37. Commenters further pointed out that the separation requirement would create “significant” ongoing costs, “including contracts for goods and services and staff time,” that “the Department fails to acknowledge in the first year and every subsequent year.” Rich Decl., Exh. M at 32.

Notwithstanding these comments, the Final Rule changed very little after receiving these comments. HHS revised its central estimate from \$20,000 per affected site to \$30,000. See 84 Fed. Reg. at 7781–82. It criticized the “extremely high cost estimates” provided by commenters as “based on assumptions that they would have to build new facilities in order to comply with the requirements for physical separation.” *Id.* at 7781. The agency suggested that “entities will usually choose the lowest cost method to come into compliance,” such as “shift[ing] their abortion services, and potentially other services not financed by Title X, to distinct [existing] facilities, a change which likely entails only minor costs.” *Id.* This suggestion ignores that commenters had already addressed the possibility of “renovating facilities in order to comply,” short of building new ones, and still concluded that renovation costs vastly exceeded the agency’s estimates. Rich Decl., Exh. M at 31. Moreover, HHS’s claim that shifting existing services “entails only

minor costs” is wholly conclusory. Its final estimate of \$30,000 per site has no more discernible evidentiary basis than its initial estimate of \$20,000—a figure seemingly pulled from thin air—and is an order of magnitude lower than the evidence-backed calculations provided by commenters. Furthermore, HHS also offered no response to commenters’ descriptions of their ongoing compliance costs beyond the first year.

HHS also ignored consequential costs of compliance. Numerous commenters explained to HHS that because compliance with the physical separation requirement would be “prohibitive in terms of cost and feasibility” large numbers of Title X providers would be forced to leave the program. Rich Decl., Exh. L at 16–17, Exh. C at 16–17, Exh. G at 11–12, Exh. H at 10–11, Exh. M at 32–34. Plaintiffs have provided ample evidence demonstrating that without Title X funding, these providers would be able to serve far fewer clients, including evidence that Title X funds services for more than 1 million patients in California every year, and that 85 percent of Essential Access subrecipients will have to lay off staff and cut services and programming without Title X funding. See Part III.A.1., *supra*; Rabinovitz Decl. ¶¶ 1, 14–15. The withdrawal of Planned Parenthood alone would create a massive vacuum in services as its health centers currently serve more than 40% of all Title X patients. Rich Decl., Exh. M at 15–16. “[O]ther types of Title X sites would need to increase their client caseloads by 70 percent” just to make up for the shortfall created by Planned Parenthood’s departure. *Id.* at 16. “[T]he departure of a large number of Title X-funded providers ... would reduce access to family planning care with attendant negative impacts on health outcomes and population health. *Id.* at 33. The “adverse health consequences” to patients would include “unintended pregnancies, undetected STDs, and other poor health outcomes.” *Id.*; see *id.*, Exh. G at 12–13; U.S. Dep’t of Health and Human Services, *Title X Family Planning Annual Report: 2016 National Summary* at 1 (2017) (“For many clients, Title X providers are their only ongoing source of health care and health education.”), <https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf>. Further, the physical separation requirement would “force patients to make multiple appointments and trips” for their family planning needs, Rich Decl., Exh. C at 17, creating “unnecessary costs to patients and providers” and “interfer[ing] with the integration of care,” *id.*, Exh. M at 33–34. While these costs are more difficult to estimate given their consequential nature, HHS largely ignored these potentially enormous costs.

*34 Instead, in response, HHS cites only a “Christian

Medical Association and Freedom2Care poll conducted on May 3, 2011, which found that 91 percent of physicians who practiced medicine based on the principles of their faith said they would be forced to leave medicine if coerced into violating the faith tenets and medical ethics principles that guide their practice of medicine.” 84 Fed. Reg. at 7780 n.138. Based on this poll, the agency suggests that “[w]ith the final rule’s added emphasis on protecting rights of conscience, more individuals may enter the Title X family planning program, helping to meet that unmet need for care.” *Id.* at 7781. The flaws in this leap of logic are myriad. Fundamentally, the poll did not ask doctors anything about Title X specifically. For example, does the permissive ability to provide nondirective abortion counseling and referral actually violate their beliefs? Have the 2000 regulations deterred them from participating in Title X because of their beliefs? Would they join Title X projects if they were not required to provide nondirective counseling and referral for abortions? More to the point, have these doctors been deterred from joining Title X projects because other projects do not have physically separate facilities? On its face, this would seem to be a non-sequitur. There is particular reason to question the assumption that large numbers of doctors are being discouraged from joining Title X because of their beliefs about abortion because HHS has already implemented rules that, since 2008, have recognized that Title X program requirements must be enforced consistent with federal laws that protect moral and religious conscience. See 73 Fed. Reg. 78072 (2008); 76 Fed. Reg. 9968 (2011). In any event, there is no evidence there are enough such would-be doctors who would be prompted by the Final Rule to join Title X to fill the vacuum left by exiting providers. HHS offers no other data or evidence in support of its momentous claim that “the final rule will contribute to more clients being served, gaps in services being closed, and improved client care.” 84 Fed. Reg. at 7766.

HHS’s conclusory response to commenters’ evidence-backed concerns about the serious problems the physical separation requirement will cause flies in the face of established APA principles. See *McDonnell Douglas Corp. v. U.S. Dep’t of the Air Force*, 375 F.3d 1182, 1186–87 (D.C. Cir. 2004) (holding that courts “do not defer to the agency’s conclusory or unsupported suppositions”); *Occidental Petroleum Corp. v. S.E.C.*, 873 F.2d 325, 341–42 (D.C. Cir. 1989) (holding that agency’s “conclusory statement” dismissing plaintiff’s concern that public disclosure of plaintiff’s sensitive documents would cause competitive harm was so inadequate as to render the agency’s decision “unreviewable”). “[R]easonable regulation ordinarily requires paying attention to the

advantages *and* the disadvantages of agency decisions.” *Michigan v. E.P.A.*, 135 S. Ct. 2699, 2707 (2015) (emphasis in original). Here, HHS has “brushed aside critical facts,” *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017), and given “no consideration to the disruption” the physical separation requirement would cause, *Regents of Univ. of California v. United States Dep’t of Homeland Sec.*, 279 F. Supp. 3d 1011, 1045 (N.D. Cal.), *aff’d*, 908 F.3d 476 (9th Cir. 2018). As such, the promulgation of the physical separation requirement “runs counter to the evidence before the agency” and is arbitrary and capricious under traditional APA principles, *State Farm*, 463 U.S. at 43, and even more so under *Fox Television*, 556 U.S. at 515 (requiring agency to provide a “more detailed justification” for a change in policy and show “that there are good reasons” for the change).

c. The Counseling and Referral Restrictions are Arbitrary and Capricious

Plaintiffs next challenge the promulgation of the Final Rule’s restrictions on abortion counseling and referral as arbitrary and capricious. *See* California Mot. at 17–18; Essential Mot. at 17–18.

Defendants’ justification for reinstating restrictions on abortion counseling and referrals is that “the 2000 regulations are not consistent with federal conscience laws,” including “the Church Amendment, Coats-Snowe Amendment and the Weldon Amendment.” 84 Fed. Reg. at 7746; *see* Opp. at 31–32. These conscience laws do not provide a reasoned explanation for the Final Rule’s counseling restrictions for two reasons.

First, as noted above, there are already HHS regulations on the books that ensure Title X’s implementation is consistent with the conscience laws. In 2008, the agency announced that it “would not enforce [the abortion counseling and referral] requirement on objecting grantees or applicants.” 73 Fed. Reg. at 78087. This rule was partially repealed in 2011 and replaced with a “new process for enforcing those [conscience] protections” whereby the HHS Office for Civil Rights addresses any complaints of discrimination under the conscience laws. 76 Fed. Reg. at 9969. The agency emphasized that the “partial rescission of the 2008 Final Rule [in 2011] does not alter or affect the federal statutory health care provider conscience protections.” *Id.* HHS fails to explain why a more sweeping set of restrictions is necessary in

light of the existing safeguards tailored to ensure Title X’s compliance with federal conscience laws. *See Council of Parent Attorneys & Advocates, Inc. v. DeVos*, -- F. Supp. 3d --, No. 18-CV-1636 (TSC), 2019 WL 1082162, at *15 (D.D.C. Mar. 7, 2019) (holding that an agency rule is arbitrary and capricious where “the government failed to explain why the [existing] safeguards as a whole would not prevent against the risk” the rule purported to address).

*35 Second, the conscience laws prohibit federal, state, and local governments “from engaging in discrimination against a health care entity on the basis that it does not, among other things, refer for abortion.” *Id.* This means HHS may not require Title X grantees to provide abortion referrals over their objections. But this does not concern grantees which *do not* have moral or religious objections to abortion. The conscience laws do not provide a basis for HHS to bar *all* Title X grantees from providing abortion referrals. Given the lack of a reasoned basis for the counseling and referral restrictions, those provisions of the Final Rule are arbitrary and capricious under the traditional *State Farm* analysis.

As with the physical separation requirement, this aspect of the Final Rule, which significantly alters the longstanding prior regulatory scheme requires a more detailed justification under *Fox Television*. The counseling and referral restrictions are based in part on factual findings discussed in the Final Rule that contradict those which underlay the 2000 regulations. In 2000, HHS justified its formal rescission of the 1988 “gag rule” on the following grounds: it “endangers women’s lives and health by preventing them from receiving complete and accurate medical information”; it “interferes with the doctor-patient relationship by prohibiting information that medical professionals are otherwise ethically and legally required to provide to their patients”; “requiring a referral for prenatal care ... where the client rejected those options would seem coercive and inconsistent with the concerns underlying the ‘nondirective’ counseling requirement; and it is “consistent with the prevailing medical standards recommended by national medical groups.” 65 Fed. Reg. at 41270–75. In contrast, HHS now asserts the restrictions in the Final Rule are warranted because “it is not necessary for women’s health that the federal government use the Title X program to fund abortion referrals, directive abortion counseling, or give to women who seek abortion the names of abortion providers”; “[r]eferring for adoption or prenatal care, but not for abortion, does not ... make pregnancy counseling directive”; and the restrictions “will [not] require health care professionals to violate medical ethics, regulations concerning the practice of medicine, or malpractice liability standards.” 84 Fed.

Reg. at 7746–48. This factual finding conflicts with those underlying the prior HHS guidelines, so HHS must “provide a more detailed justification” for the counseling and referral restrictions. *Fox Television*, 556 U.S. at 515–16. It has not done so. The agency’s claim that the restrictions are needed for Title X to comply with conscience laws rings hollow given that its existing regulations already ensure compliance, and in any event the restrictions go far beyond what the conscience laws require.

d. The “Physician or APP” Requirement is Arbitrary and Capricious

Plaintiffs further contend that the requirement in § 59.14(b)(1)(i) that nondirective pregnancy counseling can only be “provided by physicians or advanced practice providers” is arbitrary and capricious, because there is a “complete absence of justification” for the requirement. Essential Mot. at 18; California Mot. at 18–19. Defendants offer two responses, both of which make little sense. First, Defendants point out that the Final Rule is more permissive than the Proposed Rule, because the Proposed Rule restricted pregnancy counseling to physicians only, whereas the Final Rule allows physicians and APPs to take on counseling duties. Opp. at 32–33. This observation is neither here nor there, because neither the Proposed Rule nor the Final Rule explains *why* pregnancy counseling should be limited to physicians or APPs. The physician-and-APP limitation, while more permissive than the physician-only limitation initially proposed, is just as arbitrary.

*36 Second, Defendants claim that “HHS considered which types of health care professionals to include [as qualified to provide pregnancy counseling], and reasonably drew the line at APPs, who have ‘advanced medical degrees, licensing, and certification requirements.’ ” *Id.* (quoting 84 Fed. Reg at 7728 n.41). But this merely recites the Final Rule’s definition of APP; again, Defendants cannot point to any part of the Final Rule where HHS explains *why* “advanced medical degrees, licensing, and certification requirements” are necessary to qualify someone to provide pregnancy counseling. The agency certainly did not address voluminous evidence that non-APP personnel with the proper training have long been capably providing pregnancy counseling. *See, e.g.*, Kost Decl. ¶ 86 (citing Guttmacher Institute report that in 2010, 65% of Title X sites “rel[ie]d on trained health educators, registered

nurses and other qualified providers (excluding physicians and advanced practice clinicians) to counsel patients in selecting contraceptive methods”); Forer Decl. ¶ 29. HHS apparently also disregarded its own recognition of the importance of non-APPs to Title X. *See* 84 Fed. Reg. at 7778 (reporting that non-APPs “were involved with 1.7 million Title X family planning encounters in 2016,” approximately one-quarter of the total number of Title X family planning encounters that year).

The APA requires an agency to “articulate a satisfactory explanation for its action.” *State Farm*, 463 U.S. at 43. Moreover, the change in policy based on conflicting factual findings and which engender serious reliance interests require “good reason” and a “more detailed justification.” *Fox Television*, 556 U.S. at 515. HHS has articulated no explanation at all for the APP requirement and thus fails both tests. Accordingly, Plaintiffs are likely to succeed on the merits of their claim that § 59.14(b)(1)(i) is arbitrary and capricious.

e. The Removal of the “Medically Approved” Requirement is Arbitrary and Capricious

The 2000 regulations required Title X projects to “[p]rovide a broad range of acceptable and effective *medically approved* family planning methods ... and services.” 42 C.F.R. § 59.5(a)(1) (2000) (emphasis added). The Final Rule removes the “medically approved” language; it simply requires Title X projects to “[p]rovide a broad range of acceptable and effective family planning methods ... and services.” § 59.5(a)(1). Plaintiffs argue HHS failed to provide a reasoned basis for this change. Again, they are correct.

HHS provided one justification for removing the “medically approved” language. According to the agency, “[t]he ‘medically approved’ language risked creating confusion about what kind of approval is required for a method to be deemed ‘medically approved.’ ” 84 Fed. Reg. at 7741. As Plaintiffs point out, however, HHS cannot identify a single instance in the eighteen years since the 2000 regulations added the “medically approved” requirement where a regulated entity has expressed confusion about the meaning of the term. Indeed, numerous comments submitted during rulemaking demonstrated that Title X providers understood “medically approved” to mean contraceptive methods that have been approved by the Food and Drug Administration, because that is what HHS has made clear

it means. Throughout its QFP Guidelines, HHS emphasizes repeatedly that providers of family planning services should provide “a full range of *FDA-approved* contraceptive methods.” QFP Guidelines at 7 (emphasis added); *id.* at 2, 10, 11, 23, 24, 39. Numerous medical associations and experts in reproductive health told the agency that they understood “medically approved” to mean “FDA approved.” *See, e.g.*, Rich Decl., Exh. E at 2 (Guttmacher Institute); Exh. G at 8 (ACOG); Exh. I at 3 (AMA); Exh. K at 5 (APHA).

The only confusion evinced anywhere in the record is of the agency’s own creation. In the Final Rule, instead of citing its QFP Guidelines, HHS hypothesized: “Family planning methods and services are often provided through licensed health care professionals. Thus, it is true of all family planning methods or services provided by Title X providers that at least one medical professional or clinic has ‘approved’ the method or service, by virtue of providing it to the client.” 84 Fed. Reg. at 7732. In disregarding the industry-accepted understanding of “medically approved” and instead suggesting that a single individual—who may be but is not necessarily a “licensed health care professional”—may be able to confer medical approval on a family planning method, HHS is manufacturing confusion where none previously existed. *Nat’l Fuel Gas Supply Corp. v. F.E.R.C.*, 468 F.3d 831, 837 (D.C. Cir. 2006) (finding arbitrary and capricious an agency order that the record revealed to be “a solution in search of a problem”).

*37 HHS further feigned ignorance in the Final Rule when it wrote that “[t]he Department also does not understand, and commenters fail to explain, what the addition of ‘medically approved’ to the definition would mean in practice.” 84 Fed. Reg. at 7732. But it later revealed the commenters had explained precisely the import of the “medically approved” language: “Some commenters state the language could reduce access to the safest, effective, and medically approved contraceptive methods, increase risks associated with promoting medically unreliable methods, place political ideology over science, and undermine recommendations jointly issued by OPA and the CDC on Quality Family Planning.” *Id.* at 7740. While it recited these concerns, HHS failed to address them. *See Beno v. Shalala*, 30 F.3d 1057, 1074–75 (9th Cir. 1994) (“[A] court should not infer that an agency considered an issue merely because it was raised, where there is no indication that the agency ... refuted the issue.”). Thus, the problem is not that commenters neglected their duty to raise the potential problems with removing the “medically approved” requirement; it is the fact that HHS neglected its duty under the law to consider them.

Accordingly, HHS “offered an explanation for its decision” to remove the “medically approved” language from § 59.5(a)(1) “that runs counter to the evidence before the agency,” rendering its action arbitrary and capricious. *State Farm*, 463 U.S. at 43.

f. HHS’s Cost-Benefit Analysis is Arbitrary and Capricious

Plaintiffs further contend that the Final Rule as a whole is arbitrary and capricious because HHS conducted and relied upon a deeply flawed cost-benefit analysis. It cited benefits that the Final Rule would confer without any evidentiary basis while disregarding or discounting costs that were supported by the record. *See California Mot.* at 14–18; *Essential Mot.* at 16–19; *see also* Docket No. 48-1 (amicus brief of the Institute for Policy Integrity at the New York University School of Law).

“As a general rule, the costs of an agency’s action are a relevant factor that the agency must consider before deciding whether to act,” and “consideration of costs is an essential component of reasoned decisionmaking under the Administrative Procedure Act.” *Mingo Logan Coal Co. v. Env’tl. Prot. Agency*, 829 F.3d 710, 732–33 (D.C. Cir. 2016); *see Michigan v. E.P.A.*, 135 S. Ct. 2699, 2707–08 (2015) (“Agencies have long treated cost as a centrally relevant factor when deciding whether to regulate.”). In promulgating the Final Rule, HHS conducted an economic and regulatory impact analysis as required by “Executive Order 12866 on Regulatory Planning and Review” and “Executive Order 13563 on Improving Regulation and Regulatory Review.” 84 Fed. Reg. at 7775. It relied on the cost-benefit analysis in promulgating the Final Rule. *See, e.g., id.* at 7766, 7781–82 (relying on compliance cost estimates to conclude that the new separation requirements will not “have a significant impact on access to services” and to reject commenters’ objections that the “requirements will destabilize the network of Title X providers”); *id.* at 7756, 7782–83 (relying on analysis of benefits to assert the Final Rule will “expand[] the type and nature of the Title X providers and ensur[e] the diversity of such providers so as to fill gaps and expand family planning services offered through Title X”). When an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable.” *Nat’l Ass’n of Home Builders v. E.P.A.*, 682 F.3d 1032, 1039–40 (D.C. Cir. 2012) (reviewing a

cost-benefit analysis conducted pursuant to [Executive Order 12866](#) under the arbitrary and capricious standard); *Council of Parent Attorneys*, -- F. Supp. 3d ---, 2019 WL 1082162, at *18 n.11 (same).

HHS's cost-benefit analysis is thus subject to review under the APA. Although such review is deferential, *Am. Trucking Ass'ns, Inc. v. Fed. Motor Carrier Safety Admin.*, 724 F.3d 243, 254 (D.C. Cir. 2013), the analysis conducted by HHS here fails even deferential review. On the one hand, the agency proclaimed that a myriad of benefits would flow from the Final Rule without providing any substantiating basis or analysis. On the other, HHS either ignored or dismissed out of hand evidence of the significant costs the Final Rule is likely to inflict that numerous commenters brought to its attention.

i. HHS Did Not Adequately Consider Costs to Patient and Public Health

*38 In response to the Proposed Rule, commenters submitted ample evidence to HHS that the Final Rule's costs on patients and the public will be substantial.

As previously noted, commenters provided substantial evidence that the Final Rule will drive a significant number of current Title X grantees out of the program. Planned Parenthood, whose health centers serve *over 40%* of all Title X patients, "would be forced to discontinue [its] participation in Title X if the Proposed Rule takes effect." Rich Decl., Exh. M at 15–16. Further, "a number of state grantees, including Washington, New York, Hawaii, and Oregon have already put the Department on notice that they would be forced to exit the program if the proposed regulations are finalized, along with other direct grantees." *Id.* at 15. These states combined serve 427,000 Title X patients. *Id.* The loss of Title X funding will force providers to significantly scale down their service capacity or shut down altogether. *See id.*, Exh. C at 5–6. Indeed, the Guttmacher Institute recently estimated that the exit of Planned Parenthood could lead to 1.6 million women losing access to the Title X-funded contraceptive care they currently receive. *Id.*; *see also* Part III.A.1., *supra* (detailing how California providers' capacities will be diminished without Title X funding).

In response, HHS proclaims that it "does not anticipate that there will be a decrease in the overall number of facilities offering [Title X] services, since it anticipates other, new entities will apply for funds, or seek to

participate as subrecipients, as a result of the final rule." *Id.* at 7782. As previously discussed, however, this pronouncement is wholly conclusory and unsupported. *See* Part III.A.1., *supra*. HHS provides no evidence to indicate that there are new grantees waiting in the wings to join Title X, much less enough new grantees to fill the vacuum left by the impending exodus.

Commenters also alerted HHS that the decreased access to reproductive health services precipitated by the Final Rule will lead to an increase in the number of unintended pregnancies and births. In particular, an "increase [in] unplanned and mistimed pregnancies" is a "near certainty under the proposed rule." Brindis Decl., Exh. B at 11. A 2015 Guttmacher Institute report found that "in California, across all publicly funded contraceptive providers ... it was estimated that, for every seven women who received publicly funded contraceptive services, two pregnancies were averted." *Id.* at 12 n.73. Nationwide, "Title X-funded services helped women avert an estimated 822,300 unintended pregnancies in 2015 alone, thus preventing 387,200 unplanned births and 277,800 abortions." Rich Decl., Exh. L at 31–32. Without the providers of these services, the country's unintended pregnancy rate would have increased by a *whopping 31 percent*. *Id.* The connection between decreased family planning funding and increased rates of unintended pregnancy is reinforced by two further studies. One documented a 27% increase in births among women (who had been using highly effective, publicly funded contraceptive methods) once Texas "severely restricted public funding for family planning." Brindis Decl., Exh. B at 12; *see also* Rich Decl., Exh. K at 4 (American Public Health Association comment noting that "[i]n states that have eliminated Planned Parenthood from their family planning programs, the public health results have been disastrous"). The other surveyed patients in California's publicly funded family planning program and found that individuals would resort to less effective forms of contraceptive if they were forced to pay for family planning services themselves. Brindis Decl., Exh. B at 11. Billions of dollars in public costs would be "associated with ... unintended pregnancies and outcomes." *Id.* at 12–13.

*39 At three different places in the Final Rule, HHS offers three different, seemingly conflicting responses to this evidence. All three are baseless. First, HHS claims that the Final Rule "is likely to *decrease* unintended pregnancies ... because clients are more likely to visit clinics that respect their views and beliefs and to use methods that they desire and that fit their individual circumstances." 84 Fed. Reg. at 7743 (emphasis). The agency cites as the basis for this belief § 59.5(a)(1) of the

Final Rule, which clarifies that Title X projects need not provide every family planning method or service. But HHS provides no evidence or analysis suggesting a connection between § 59.1(a)(1) and decreased unintended pregnancies. The agency does not, for example, provide any basis for believing that under the current regulations, patients are choosing not to avail themselves of Title X care because their “views and beliefs” are disrespected by clinics providing nondirective counseling.

Second, HHS insists that “[c]ommenters offer no compelling evidence that this rule will increase unintended pregnancies or decrease access to contraception.” 84 Fed. Reg. at 7785. “On the contrary,” according to the agency, “more patients could have access to services because of changes to the program.” *Id.* No explanation is offered for this conclusion, nor any analysis to support it. To the extent this conclusory assertion stems from the assumption that the Final Rule will prompt large numbers of new grantees to join Title X, that assumption is debunked by record evidence, as detailed above.

Third, HHS offers an excuse for disregarding the costs associated with higher instances of unintended pregnancies:

[T]he Department is not aware, either from its own sources or from commenters, of actual data that could demonstrate a causal connection between the type of changes to Title X regulations contemplated in this rulemaking and an increase in unintended pregnancies, births, or costs associated with either, much less data that could reliably calculate the magnitude of that hypothetical impact. Therefore, the Department concludes that those are not likely or calculable impacts for the purpose of the Executive Order.

84 Fed. Reg. at 7775. This rationale does not withstand even deferential scrutiny.

For one thing, “[t]he mere fact that the ... effect[] [of a rule] is *uncertain* is no justification for *disregarding* the effect entirely.” *Pub. Citizen v. Fed. Motor Carrier Safety*

Admin., 374 F.3d 1209, 1219 (D.C. Cir. 2004) (emphases in original). Yet that is the exact mistake HHS makes here in concluding that unintended pregnancies “are not likely” because it believes the effects of the Final Rule are difficult to quantify. HHS cannot simply disregard costs that are uncertain or difficult to quantify. Its “Guidelines for Regulatory Impact Analysis” set forth in detail how the agency is supposed to “address[] outcomes that cannot be quantified but may have important implications for decision-making.”¹⁷ HHS Guidelines at 47. Per the Guidelines, “[i]f quantification is not possible, analysts *must* determine how to best provide related information.” *Id.* (emphasis added); *see id.* at 47–51 (laying out various approaches for incorporating non-quantified effects into regulatory impact analysis). “At minimum, analysts should list significant nonquantified effects in a table and discuss them qualitatively.” *Id.* at 51. HHS failed to do even that here. In its cost-benefit accounting table, the agency listed the total “Non-quantified Costs” of the Final Rule as, simply, “None.” *Id.* at 7777. “None” more aptly describes the extent of HHS’s analysis.

*40 Commenters also informed HHS that the exodus of Title X providers will reduce patients’ access to health services beyond family planning, and give rise to attendant health costs. “Apart from the delivery of family planning care, Title X providers have come to play an essential and important role in providing any number of other vital health services for low-income Americans,” including “screenings for cervical cancer, diabetes, high blood pressures, and sexually transmitted infections (STIs), among a range of other services aimed at primary prevention and referral.” Brindis Decl., Exh. B at 3.¹⁸ “[F]or many low-income women, visits to a family planning provider are their only interaction with the health care system at all,” so a reduction in the number of Title X sites would “cut off many people” from a critical health resource. *Id.*; *see Rich Decl.*, Exh. M at 16 (Planned Parenthood comment explaining that “[f]ifty-six percent of Planned Parenthood health centers are in health provider deserts, where residents live in areas that are medically underserved and may have nowhere else to go to access essential health services without Planned Parenthood”). Commenters cited the case study of a rural Indiana county in which the Planned Parenthood facility closed in 2013 due to cuts to public health funding. Brindis Decl., Exh. B at 6. Without the facility, the county lost free HIV testing services and almost immediately experienced “one of the largest and most rapid HIV outbreaks the country has ever seen.” *Id.* at 6–7 (citation omitted).

In response to this evidence, HHS wrote:

Based on the Department’s best estimates, it anticipates that the net impact on those seeking services from current grantees *will be zero*, as any redistribution of the location of facilities will mean that some seeking services will have shorter travel times and others seeking services will have longer travel times to reach a facility. Additionally, as a result of this final rule, the Department anticipates expanded competition that will engender new and/or additional grantees who will serve previously unserved or underserved areas, likely expanding coverage and patient access to services.

84 Fed. Reg. at 7782 (emphasis added).

The agency did not explain how it arrived at its “best estimates,”¹⁹ or how it reached the seemingly speculative conclusion that the Final Rule would result merely in the “redistribution” of services and that because of the entrance of new grantees “the net impact on those seeking services from current grantees will be zero.” The lack of any evidence or analysis supporting HHS’s supposition that everything will even out is particularly conspicuous in the face of evidence that “other types of Title X sites would need to increase their client caseloads by 70 percent” just to compensate for the exit of Planned Parenthood from Title X. Rich Decl., Exh. M at 16. HHS’s “naked conclusion ... is not enough.” *United Techs. Corp. v. U.S. Dep’t of Def.*, 601 F.3d 557, 565 (D.C. Cir. 2010).

HHS similarly failed to take account of the costs that will result from its decision to remove the requirement in § 59.5(a)(1) that the family planning methods and services provided under Title X be “medically approved.” Commenters notified the agency that this change “could reduce access to the safest, effective, and medically approved contraceptive methods, increase risks associated with promoting medically unreliable methods, place political ideology over science, and undermine recommendations jointly issued by OPA and the CDC on Quality Family Planning.” 84 Fed. Reg. at 7740; see Rich Decl., Exh. I at 3; *id.*, Exh. Q at 2. Commenters specifically warned HHS that the change “seem[s] to open the door to entities like antiabortion counseling centers (or ‘crisis pregnancy centers’)” that “commonly do not have any medical staff and are not able or willing to provide

many or all modern and FDA-approved methods of contraception.” Rich Decl., Exh. E at 15. The agency did not address any of these potential costs to patient health.

ii. HHS Did Not Adequately Consider Compliance Costs

*41 HHS’s assessment of the costs to regulated entities of complying with the Final Rule is also inadequate, for the reasons discussed in Part III.C.2.b., *supra*.

iii. The Claimed Benefits are Unsubstantiated and Speculative

On the other side of the cost-benefit equation, HHS contends that the Final Rule is expected to “[e]nhance[] compliance with statutory requirements”; result in an “[e]xpanded number of entities interested in participating in Title X”; and “[e]nhance[] patient service and care.” 84 Fed. Reg. at 7777, 7782. But HHS provided no evidence in support of any of these claims; nor did it provide any estimates of the expected magnitude of these supposed benefits. Instead, each of these claimed benefits has been shown to “run[] counter to the evidence before the agency.” *State Farm*, 463 U.S. at 43. In the absence of any attempt by HHS to quantify or even explain with any substantive analysis the Final Rule’s claimed benefits, it cannot be said that there has been a “reasoned determination” that the benefits justify the costs. “[R]easoned decisionmaking requires assessing whether a proposed action would do more good than harm.” *Mingo Logan Coal Co. v. Envtl. Prot. Agency*, 829 F.3d 710, 732 (D.C. Cir. 2016).

On the whole, the determination by HHS that the asserted but unsubstantiated, undocumented, and speculative benefits of the Final Rule outweigh its likely substantial costs indicates the agency “put a thumb on the scale by [over]valuing the benefits and [under]valuing the costs.” *Ctr. for Biological Diversity v. Nat’l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008). The cost-benefit analysis is undermined by “serious flaw[s]” that “render the rule unreasonable” in its entirety under the APA. *Nat’l Ass’n of Home Builders*, 682 F.3d at 1039–40; see *State v. United States Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1123 (N.D. Cal. 2017) (holding that agency action was arbitrary and capricious

where the agency “only consider[ed] one side of the equation” in its cost-benefit analysis).

3. HHS Did Not Violate Notice and Comment Procedures

Essential Access makes one final claim under the APA. It contends that Defendants did not comply with the APA’s notice and comment requirements because the “comprehensive primary care provider” and “physician and APP” requirements in the Final Rule are not logical outgrowths of the proposed rule. *See* Essential Mot. at 19–20.

The APA generally requires an agency to engage in notice and comment as part of its rulemaking process. *See* 5 U.S.C. § 553(b). The agency must publish a notice of proposed rulemaking in the Federal Register and notify the public of, *inter alia*, “the terms or substance of the proposed rule or a description of the subjects and issues involved.” *Id.* § 553(b)(3). “Agencies are free—indeed, they are encouraged—to modify proposed rules as a result of the comments they receive.” *Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 951 (D.C. Cir. 2004). However, “an agency’s proposed rule and its final rule may differ only insofar as the latter is a ‘logical outgrowth’ of the former.” *Env’tl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (citation omitted). A final rule is considered a logical outgrowth of a proposed rule “only if interested parties ‘should have anticipated’ that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period.” *Int’l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005) (quoting *Ne. Md. Waste Disposal Auth.*, 358 F.3d at 952); *Env’tl. Def. Ctr., Inc. v. U.S. E.P.A.*, 344 F.3d 832, 851 (9th Cir. 2003).

a. The “Comprehensive Primary Care Provider” Requirement is a Logical Outgrowth of the Proposed Rule

*42 According to Essential Access, the requirement in § 59.14(b)(1)(ii) of the Final Rule that Title X projects can only refer patients to “licensed, qualified, comprehensive primary health care providers” is not a logical outgrowth of the Proposed Rule, which permitted referrals to

“licensed, qualified, comprehensive health service providers.” 83 Fed. Reg. at 25531. That is, Essential Access objects that the Proposed Rule did not specify that “comprehensive health service providers” must provide “primary care services.” Essential Mot. at 20.

Essential Access has not cited any authority for the proposition that “comprehensive primary care” is meaningfully different from “comprehensive care,” such that interested parties could not have anticipated that the Final Rule would incorporate the former term. Essential Access insists that language in the Final Rule “contemplates that ‘comprehensive’ health care services can be ‘primary’ or ‘prenatal.’ ” Essential Reply at 8 (citing 84 Fed. Reg. at 7761). But the actual language in the Final Rule does not draw a distinction between “primary” comprehensive care and “prenatal” comprehensive care; it merely indicates that “comprehensive primary care” can include prenatal care. *See* 84 Fed. Reg. at 7761 (“The Department is finalizing § 59.14(b)(1)(ii) to allow Title X providers to give a single list of providers to any pregnant woman. This list will contain licensed, qualified, comprehensive primary health care providers (including providers of prenatal care).”). Essential Access has not shown a likelihood of success on its claim that § 59.14(b)(1)(ii) of the Final Rule is not a logical outgrowth of the Proposed Rule.

b. The “Physician or APP” Requirement is a Logical Outgrowth of the Proposed Rule

Essential Access also argues the requirement in § 59.14(b)(1) of the Final Rule that any nondirective pregnancy counseling under Title X can only be “provided by physicians or advanced practice providers” is not a logical outgrowth of the Proposed Rule. Essential Mot. at 20. It is true, as Essential Access points out, that the term “advanced practice provider” does not appear anywhere in the Proposed Rule. But that is because the Proposed Rule was more restrictive than the Final Rule; under the former, only physicians were permitted to provide pregnancy counseling:

[A] doctor, though not required to do so, would be permitted to provide nondirective counseling on abortion. Such nondirective counseling would not be considered

encouragement, promotion, or advocacy of abortion as a method of family planning, as prohibited under section 59.16 of this proposed rule. Moreover, a doctor would also be permitted to provide a list of licensed, qualified, comprehensive health service providers, some (but not all) of which provide abortion in addition to comprehensive prenatal care.

83 Fed. Reg. at 25518. In summarizing the changes between the Proposed Rule and the Final Rule, HHS wrote, “as a result of comments on the type of medical professional who could provide nondirective counseling and referrals under the proposed rule, ... the Department has determined that, in addition to medical doctors, advanced practice providers (APPs) may provide nondirective counseling and referrals.” 84 Fed. Reg. at 7727–28.

The Proposed Rule signaled that the agency was considering limiting counseling responsibilities to individuals with advanced medical degrees, so it cannot be said that the Final Rule “finds no roots in the agency’s proposal.” *Env’tl. Integrity Project v. E.P.A.*, 425 F.3d 992, 996 (D.C. Cir. 2005); see *Hodge v. Dalton*, 107 F.3d 705, 712 (9th Cir. 1997) (holding that a final rule “in character with the original proposal” is a logical outgrowth). Moreover, the Final Rule indicates that the Proposed Rule engendered “comments on the type of medical professional who could provide nondirective counseling and referrals.” 84 Fed. Reg. at 7727–28. Essential Access argues that “[h]ad HHS provided proper notice, the public may have expressed concerns ... [that] the definition of APP is much too narrow, and excludes professionals who currently provide the bulk of pregnancy options counseling at Title X centers.” Essential Mot. at 20. However, any such comments about the ability of certain categories of professionals to provide counseling could equally have been submitted to the Proposed Rule because those professionals were already excluded under the Proposed Rule.

*43 Accordingly, Essential Access has not shown that a likelihood that § 59.14(b)(1) of the Final Rule is not a logical outgrowth of the Proposed Rule.

4. Plaintiffs’ Remaining Claims

Because the Court finds that Plaintiffs have established that they are likely to succeed on the merits of their “not in accordance with law” and “arbitrary and capricious” claims under the APA, the Court will not reach their constitutional claims at this time.

D. Scope of Injunction

Plaintiffs have made a strong showing on each of the *Winter* factors, and accordingly are entitled to preliminary relief. They ask the Court to grant a nationwide injunction. California Mot. at 25; Essential Mot. at 33–35. Defendants respond that any injunctive relief should be limited to Plaintiffs, *i.e.*, to the state of California. Opp. at 46–50.

The recent Ninth Circuit ruling in *California v. Azar*, 911 F.3d 558 (9th Cir. 2018) provides guidance on how a district court should exercise its discretion in crafting an injunction. *Azar* emphasized that while “ ‘there is no bar against ... nationwide relief in federal district court or circuit court,’ such broad relief must be ‘necessary to give prevailing parties the relief to which they are entitled.’ ” *Id.* at 582 (quoting *Bresgal v. Brock*, 843 F.2d 1163, 1170–71 (9th Cir. 1987)). The Ninth Circuit determined that the nationwide injunction it was reviewing was overbroad because “while the record before the district court was voluminous on the harm to the plaintiffs, it was not developed as to the economic impact on other states.” *Id.* at 584. The court instructed that “[d]istrict judges must require a showing of nationwide impact or sufficient similarity to the plaintiff states to foreclose litigation in other districts.” 911 F.3d at 584.

Plaintiffs have supplied ample evidence of the Final Rule’s anticipated impact within California. See Part III.A., *supra*. They offer three reasons why a nationwide injunction is necessary to afford them adequate relief. First, they assert that any violation of the APA “compel[s]” a nationwide injunction. Essential Reply at 14. Notably, however, *Azar* found that the plaintiffs there had shown a likelihood of success on their APA claims, and nonetheless ruled that a nationwide injunction was overbroad. See 911 F.3d at 575–81. This suggests that, notwithstanding an APA violation, this Court still must assess whether “[t]he circumstances of this case dictate a narrower scope” of relief. *Id.* at 584.

Plaintiffs’ second argument is that they *have* provided sufficient evidence of the Final Rule’s nationwide impact to support a broad injunction, and in particular cite to the

Kost and Brindis declarations. *See* Essential Reply at 15 (citing Kost Decl. ¶¶ 76–78; Brindis Decl. ¶¶ 80–93). While the portions of the declaration on which Plaintiffs rely address the many Title X providers around the country will leave the program because of the Final Rule, the record does not indicate that preserving the current Title X network in other states is “necessary to redress the injury shown by the [P]laintiffs[.]” *Azar*, 911 F.3d at 584 (emphasis added). Both Plaintiffs are from California. Neither Plaintiff has offices or operations outside of California. And nearly all the harms they document are focused on California. *See, e.g.*, Cantwell Decl. ¶ 32; Tosh Decl. ¶ 52. It is difficult to conduct a balance of hardship as to effects outside of California on this record.

*44 Third, Plaintiffs argue that “Title X funding recipients draw from a single pool of funding, such that ‘[t]he conditions imposed on one can impact the amounts received by others.’” California Reply at 15 (quoting *City of Chicago v. Sessions*, 888 F.3d 272, 292 (7th Cir. 2018)). According to Plaintiffs, recipients of Title X funding are “interconnected” because if Title X grantees in some areas claim less funding, grantees in other areas would receive commensurately more. Even so, however, an injunction limited to California would allow grantees within the state to maintain and deploy their regular

allotment of Title X funds; grantees in other states would not be able to take away California’s funds. It is difficult to discern on this record how a preliminary injunction limited to California will affect other states in a way that will harm Plaintiffs and their clients in California. In short, Plaintiffs have not shown at this juncture that a nationwide injunction is necessary to protect their interests. The Court cannot find, on this record, that Plaintiffs have made “a showing of nationwide impact” to warrant nationwide relief. *Azar*, 911 F.3d at 583.

Accordingly, Plaintiffs’ motions for preliminary injunction are **GRANTED** and the Final Rule is **ENJOINED** as to enforcement in the state of California.

This order disposes of *California* Docket No. 26 and *Essential Access* Docket No. 25.

IT IS SO ORDERED.

All Citations

Slip Copy, 2019 WL 1877392

Footnotes

- 1 The recent injunction issued against Defendants’ implementation of the Final Rule by Judge Bastian in *State of Washington v. Azar*, No. 1:19-cv-3040 (E.D. Wash. filed Mar. 5, 2019), does not obviate this Court’s duty to resolve the dispute before it. *See Batalla Vidal v. Nielsen*, 279 F. Supp. 3d 401, 435 (E.D.N.Y. 2018) (finding “no authority for the proposition that Plaintiffs cannot establish irreparable harm simply because another court has already enjoined the same challenged action”); *e.g.*, *Kravitz v. United States Dep’t of Commerce*, 366 F. Supp. 3d 681 (D. Md. 2019); *State v. Ross*, 358 F. Supp. 3d 965, 1050 (N.D. Cal. 2019); *Nat’l Ass’n for the Advancement of Colored People v. Trump*, 315 F. Supp. 3d 457, 461 (D.D.C. 2018).
- 2 Unless otherwise indicated, all citations in the form of “§ ____” are to the Final Rule published at 84 Fed. Reg. at 7786–91.
- 3 An exception is made for grantees with moral and religious objections to abortion. *See* 76 Fed. Reg. 9968 (2011).
- 4 Given the lack of evidence that new grantees will enter the Title X program, it is hardly surprising that Defendants do not appear to have considered how much time it would take these hypothetical new grantees to become operational Title X providers, and what the impact on patients might be from even a temporary disruption in services.
- 5 The Final Rule sets a compliance date for the physical separation requirement of March 4, 2020. 84 Fed. Reg. at 7791. But of course, grantees will have to begin the process for bringing their operations into compliance far before that.
- 6 California’s complaint also alleges that the Final Rule denies women equal protection of the laws in violation of the Fifth Amendment. *See California* Docket No. 1 ¶¶ 221–29. However, California does not rely on that claim in its preliminary injunction motion.
- 7 Apart from the brief period when the 1988 regulations were effective, HHS has consistently interpreted Section 1008 to allow nondirective pregnancy counseling.
- 8 Section 254c-6(a)(1) was enacted in 2000, four years after the Nondirective Counseling Provision was first enacted. As

noted above, the Nondirective Counseling Provision has been included in every HHS Appropriations Act since 1996, including from 2000 to 2019.

- 9 The OPA website continues to refer providers of family planning services to these guidelines. See HHS Office of Population Affairs, Quality Family Planning, <https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html> (last visited April 2, 2019) (“The QFP provide recommendations for use by all reproductive health and primary care providers with patients who are in need of services related to preventing or for achieving pregnancy.”).
- 10 Understanding referral to be a part of the counseling process also conforms to common sense. A patient would presumably be rather taken aback if, for instance, upon receiving an initial [diagnosis of cancer](#) from her doctor, the doctor then refuses to provide a referral for further testing and medically appropriate treatment.
- 11 The overlapping prohibition on abortion referrals in [§ 59.5\(a\)\(5\)](#) violates the Nondirective Counseling Provision for the same reason. See [§ 59.5\(a\)\(5\)](#) (Title X projects may “[n]ot provide, promote, refer for, or support abortion as a method of family planning.”).
- 12 Notably, HHS specifically discussed Section 1554 in a concurrent rulemaking. See [83 Fed. Reg. 57536, 57551–52 \(2018\)](#).
- 13 After it received commenters’ objections that the referral restrictions “will deprive women of the information they need about abortion or where to obtain one,” HHS offered a rather astonishing response: “[I]n the Department’s view, it is not necessary for women’s health that the federal government use the Title X program to ... give to women who seek abortion the names of abortion providers. Information about abortion and abortion providers is *widely available and easily accessible, including on the internet.*” [84 Fed. Reg. at 7746](#) (emphasis added). The Court does not share Defendants’ belief that misleading counseling provided by a medical professional is rendered harmless by information available “on the internet.”
- 14 Courts have long recognized that “in matters concerning sexual conduct, minors frequently are reluctant, either because of embarrassment or fear, to inform their parents of medical conditions relating to such conduct, and consequently that there is a considerable risk that minors will postpone or avoid seeking needed medical care if they are required to obtain parental consent before receiving medical care for such conditions.” [Am. Acad. of Pediatrics v. Lungren](#), 16 Cal. 4th 307, 317–18 (1997); [Ballard v. Anderson](#), 4 Cal. 3d 873, 880 (1971) (“[A]n unmarried pregnant minor understandably might be reluctant to seek parental consent for medical care related to her pregnancy and that the parents of such a minor might refuse consent for reasons unrelated to the health of the minor.”).
- 15 To the extent there may have been isolated instances of misuse or co-mingling of Title X funds in the past that were not cited in the Final Rule, there is no indication they escaped detection from the financial audits conducted under the 2000 regulations.
- 16 HHS’s own “Guidelines for Regulatory Impact Analysis” (“HHS Guidelines”) set forth in ample detail how the agency should estimate the costs for “[r]egulated entities ... to comply with regulatory requirements.” U.S. Dep’t of Health and Human Services, *Guidelines for Regulatory Impact Analysis* at 32 (2016), https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf. These costs explicitly include “purchasing computers and software to support administrative tasks,” “installing or retrofitting new equipment,” “capital expenditures to acquire buildings or land,” and “annual costs of labor, utilities, and other resources.” *Id.* at 32–33. The HHS Guidelines teach that “analysts generally use market data to estimate such costs.” *Id.* Here, HHS referenced no data, market or otherwise, as the basis for its compliance cost estimates.
- 17 Notably, the HHS Guidelines specifically list changes in “the type or quality of information available and its dissemination” effectuated by an agency action as a type of cost that is difficult to quantify but that HHS must nevertheless analyze. HHS Guidelines at 48. Absent from the Final Rule, however, is any substantive discussion of how the Final Rule’s counseling and referral restrictions might create informational costs.
- 18 HHS itself trumpets these benefits of the current Title X program. See Office of Population Affairs, *Title X Family Planning Annual Report 2017 Summary ES-2*, (August 2018) (“Title X-funded cervical and [breast cancer](#) screening services are necessary for early detection and treatment,” and “Title X-funded STD and HIV services provide testing necessary for preventing disease transmission and adverse health consequences.”).
- 19 The HHS Guidelines expressly describe “reductions in government payments to hospitals” as a type of “transfer cost” that “should be addressed in the benefit-cost analysis, if significant,” because “the affected hospitals may accept fewer

patients or use less expensive treatments, in turn affecting health outcomes.” HHS Guidelines at 23.

FILED IN THE
U.S. DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

Apr 25, 2019

SEAN F. MCAVOY, CLERK

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, in his official
capacity as Secretary of the United States
Department of Health and Human
Services; and UNITED STATES
DEPARTMENT OF HEALTH AND
HUMAN SERVICES,

Defendants.

No. 1:19-cv-03040-SAB

**ORDER GRANTING
PLAINTIFFS' MOTIONS FOR
PRELIMINARY INJUNCTION**

NATIONAL FAMILY PLANNING &
REPRODUCTIVE HEALTH
ASSOCIATION, FEMINIST WOMEN'S
HEALTH CENTER, DEBORAH OYER,
M.D. and TERESA GALL, F.N.P.,

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity
as Secretary of the United States

1 Department of Health and Human
2 Services; and UNITED STATES
3 DEPARTMENT OF HEALTH AND
4 HUMAN SERVICES, DIANE FOLEY,
5 M.D., in her official capacity as Deputy
6 Assistance Secretary for Population
7 Affairs, and OFFICE OF POPULATION
8 AFFAIRS,
9 Defendants.
10

11 Before the Court are Plaintiffs’ Motions for Preliminary Injunction, ECF
12 Nos. 9 and 18. A hearing on the motions was held on April 25, 2019. The State of
13 Washington was represented by Jeffrey Sprung, Kristin Beneski and Paul Crisalli.
14 Plaintiffs National Family Planning and Reproductive Health Association, *et al.*,
15 (NFPRHA) were represented by Ruth Harlow, Fiona Kaye, Brigitte Amiri,
16 Elizabeth Deutsch, and Joseph Shaeffer. Defendants were represented by Bradley
17 Humphreys. The Court also received *amicus* briefs from American Academy of
18 Pediatrics, *et al.*; Institute of Policy Integrity; State of Ohio, *et al.*, and Susan B.
19 Anthony List. This Order memorializes the Court’s oral ruling.

20 **Introduction**

21 Plaintiffs seek to set aside the Office of Population Affairs (OPA),
22 Department of Health and Human Services (“Department”) March 4, 2019 Final
23 Rule that revises the regulations that govern Title X family planning programs. 84
24 Fed. Reg. 77141-01, 2019 WL 1002719 (Mar. 4, 2019). The new regulations were
25 proposed to “clarify grantee responsibilities under Title X, to remove the
26 requirement for nondirective abortion counseling and referral, to prohibit referral
27 for abortion, and to clarify compliance obligations under state and local laws . . .
28 to clarify access to family planning services where an employer exercises a

1 religious and moral objection . . . and to require physical and financial separation
2 to ensure clarity regarding the purpose of Title X and compliance with the
3 statutory program integrity provisions, and to encourage family participation in
4 family planning decisions, as required by Federal law.” *Id.*

5 Plaintiffs contend the Final Rule is in excess of the agency’s statutory
6 authority, is arbitrary and capricious, violates the Administrative Procedures Act,
7 violates Title X requirements, violates congressional Non-directive Mandates,
8 violates Section 1554 of the Patient Protection and Affordable Care Act (“ACA”),
9 and is otherwise unconstitutional.

10 Plaintiffs assert the Final Rule is not designed to further the purposes of
11 Title X, which is to equalize access to comprehensive, evidence-based, voluntary
12 family planning. Rather it is designed to exclude and eliminate health care
13 providers who provide abortion care and referral—which by extension will impede
14 patients’ access to abortion—even when Title X funds are not used to provide
15 abortion care, counseling or referral.

16 Plaintiffs also believe the Final Rule appears to be designed to limit
17 patients’ access to modern, effective, medically approved contraception and family
18 planning health care. Plaintiffs argue the Final Rule was designed by the
19 Department to direct Title X funds to providers who emphasize ineffective and
20 inefficient family planning.

21 Finally, Plaintiffs believe the Final Rule is politically motivated and not
22 based on facts. Instead, it intentionally ignores comprehensive, ethical, and
23 evidence-based health care, and impermissibly interferes with the patient-doctor
24 relationship.

25 Defendants assert the Final Rule adopted by the Secretary is consistent with
26 the Administrative Procedures Act, consistent with Title X, the Non-directive
27
28

1 Mandates, and Section 1554 of the ACA¹, and is otherwise constitutional.

2 Defendants believe the Final Rule is indistinguishable from regulations
3 adopted over 30 years ago, which were held to be valid by the United States
4 Supreme Court in *Rust v. Sullivan*, 500 U.S. 173 (1991). Finally, Defendants argue
5 Plaintiffs have not shown, at this early stage in the litigation, that the Final Rule
6 violates Section 1008 of Title X—in fact, Plaintiffs cannot make that showing—
7 primarily because of *Rust*.

8 At issue in this hearing are Plaintiffs’ Motions for Preliminary Injunction.
9 The Final Rule is scheduled to take effect on May 3, 2019. Plaintiffs seek to
10 preserve the status quo pending a final determination on the merits.

11 **Motion Standard**

12 “A preliminary injunction is a matter of equitable discretion and is ‘an
13 extraordinary remedy that may only be awarded upon a clear showing that a
14 plaintiff is entitled to such relief.’” *California v. Azar*, 911 F.3d 558, 575 (9th Cir.
15 2018) (quoting *Winter v. NRDC*, 555 U.S. 7, 22 (2008)). “A party can obtain a
16 preliminary injunction by showing that (1) it is ‘likely to succeed on the merits,’
17 (2) it is ‘likely to suffer irreparable harm in the absence of preliminary relief,’ (3)
18 ‘the balance of equities tips in [its] favor,’ and (4) ‘an injunction is in the public
19 interest.’” *Disney Enters., Inc. v. VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir. 2017)
20 (alteration in original) (quoting *Winter*, 555 U.S. at 20). The Ninth Circuit uses a
21 “sliding scale” approach in which the elements are “balanced so that a stronger
22

23 ¹ Defendants also argue Plaintiffs have waived their argument that the Final Rule
24 violates Section 1554 of the ACA by failing to refer to Section 1554 in their
25 comments prior to the Final Rule being published. It is doubtful that an APA claim
26 asserting that an agency exceeded the scope of its authority to act can be waived.
27 Moreover, it appears that during the rule making process the agency was apprised
28 of the substance of the violation.

1 showing of one element may offset a weaker showing of another.” *Hernandez v.*
2 *Sessions*, 872 F.3d 976, 990 (9th Cir. 2017) (quotation omitted). When the
3 government is a party, the last two factors merge. *Drakes Bay Oyster Co. v. Jewell*,
4 747 F.3d 1073, 1092 (9th Cir. 2014). This means that when the government is a
5 party, the court considers the balance of equities and the public interest together.
6 *Azar*, 911 F.3d at 575. “[B]alancing the equities is not an exact science.” *Id.*
7 (quoting *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 609 (1952)
8 (Frankfurter, J., concurring) (“Balancing the equities . . . is lawyers’ jargon for
9 choosing between conflicting public interests”)).

10 Likelihood of success on the merits is the most important factor; if a movant
11 fails to meet this threshold inquiry, the court need not consider the other factors.
12 *Disney*, 869 F.3d at 856 (citation omitted). A plaintiff seeking preliminary relief
13 must “demonstrate that irreparable injury is likely in the absence of an injunction.”
14 *Winter*, 555 U.S. at 22. The analysis focuses on irreparability, “irrespective of the
15 magnitude of the injury.” *Simula, Inc. v. Autoliv, Inc.*, 175 F.3d 716, 725 (9th Cir.
16 1999). Economic harm is not normally considered irreparable. *L.A. Mem’l*
17 *Coliseum Comm’n v. Nat’l Football League*, 634 F.2d 1197, 1202 (9th Cir. 1980).

18 “[I]njunctive relief should be no more burdensome to the defendant than
19 necessary to provide complete relief to the plaintiffs’ before the Court.” *L.A.*
20 *Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 664 (9th Cir. 2011) (quoting
21 *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). This is particularly true where
22 there is no class certification. *See Easyriders Freedom F.I.G.H.T. v. Hannigan*, 92
23 F.3d 1486, 1501 (9th Cir. 1996) (“[I]njunctive relief generally should be limited to
24 apply only to named plaintiffs where there is no class certification.”); *Meinhold v.*
25 *U.S. Dep’t of Defense*, 34 F.3d 1469, 1480 (9th Cir.1994) (district court erred in
26 enjoining the defendant from improperly applying a regulation to all military
27 personnel (citing *Califano*, 442 U.S. at 702)).

1 That being said, there is no bar against nationwide relief in the district
2 courts or courts of appeal, even if the case was not certified as a class action, if
3 such broad relief is necessary to give prevailing parties the relief to which they are
4 entitled. *Bresgal v. Brock*, 843 F.2d 1163, 1170–71 (9th Cir. 1987).

5 **Federal Administrative Agency Rule-Making**

6 Federal administrative agencies are required to engage in “reasoned
7 decisionmaking.” *Michigan v. E.P.A.*, ___ U.S. ___, 135 S.Ct. 2699 (2015). “Not
8 only must an agency’s decreed result be within the scope of its lawful authority,
9 but the process by which it reaches that result must be logical and rational.” *Id.*
10 (quoting *Allentown Mack Sales & Service, Inc. v. NLRB*, 522 U.S. 359, 374
11 (1998)).

12 **Administrative Procedures Act**

13 The Administrative Procedure Act “sets forth the full extent of judicial
14 authority to review executive agency action for procedural correctness.” *FCC v.*
15 *Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009). Under the arbitrary and
16 capricious standard contained in the APA, a reviewing court may not set aside an
17 agency rule that is rational, based on consideration of the relevant factors and
18 within the scope of the authority delegated to the agency by the statute. *Motor*
19 *Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42
20 (1983). “The scope of review under the ‘arbitrary and capricious’ standard is
21 narrow and a court is not to substitute its judgment for that of the agency.
22 Nevertheless, the agency must examine the relevant data and articulate a
23 satisfactory explanation for its action including a rational connection between the
24 facts found and the choice made.” *Id.* at 43. (quotation omitted). An agency rule is
25 arbitrary and capricious “if the agency has relied on factors which Congress has
26 not intended it to consider, entirely failed to consider an important aspect of the
27 problem, offered an explanation for its decision that runs counter to the evidence
28 before the agency, or is so implausible that it could not be ascribed to a difference

1 in view or the product of agency expertise.” *Id.*

2 An agency must consider and respond to significant comments received
3 during the period for public comment. *Perez v. Mortgage Bankers Ass’n*, ___
4 U.S. ___, 135 S.Ct. 1199, 1203 (2015). The public interest is served by compliance
5 with the APA. *Azar*, 911 F.3d at 581. “The APA creates a statutory scheme for
6 informal or notice-and-comment rulemaking reflecting a judgment by Congress
7 that the public interest is served by a careful and open review of proposed
8 administrative rules and regulations.” *Alcaraz v. Block*, 746 F.2d 593, 610 (9th
9 Cir. 1984) (internal quotation marks and citation omitted). “It does not matter that
10 notice and comment could have changed the substantive result; the public interest
11 is served from proper process itself.” *Azar*, 911 F.3d at 581.

12 **History of Title X**

13 “*No American woman should be denied access to family planning assistance*
14 *because of her economic condition.*”²

15 In 1970, Congress created the Title X program³ to address low-income
16 individuals’ lack of equal access to the same family planning services, including
17 modern, effective medical contraceptive methods such as “the Pill,” available to
18 those with greater economic resources. NFPRHA, *et al.* Complaint, 1:19-cv-3045-
19 SAB, ECF No. 1, ¶4. Title X monetary grants support family planning projects
20 that offer a broad range of acceptable and effective family planning methods and
21 services to patients on a voluntary basis, 42 U.S.C. § 300(a), creating a nationwide
22 of Title X health care providers. *Id.* at ¶5. Title X gives those with incomes below
23 or near the federal poverty level free or low-cost access to clinical professional,
24

25 ² President Nixon, *Special Message to the Congress on Problems of Population*
26 *Growth* (July 18, 1969).

27 ³ Title X became law as part of the “Family Planning Services and Population
28 Research Act of 1970.” Pub. L. No. 91-572, 84 Stat. 1504 (1970).

1 contraceptive methods and devices, and testing and counseling services related to
2 reproductive health, including pregnancy testing and counseling. *Id.* Over almost
3 five decades, Title X funding has built and sustained a national network of family
4 planning health centers that delivers high-quality care. *Id.* at ¶41. It has enabled
5 millions of low-income patients to prevent unintended pregnancies and protect
6 their reproductive health. *Id.* Approximately 90 federal grants, totaling
7 approximately \$260 million, for Title X projects now fund more than 1000
8 provider organizations across all the states and in the U.S. territories, with more
9 than 3800 health centers offering Title X care. *Id.* at ¶6, ¶52. In 2017, the Title X
10 program served more than four million patients. *Id.*

11 Washington’s Department of Health (“DOH”) Family Planning Program is
12 the sole grantee of Title X funds in Washington State. Decl. of Cynthia Harris,
13 ECF No. 11 at ¶14. It provides leadership and oversight to its Family Planning
14 Network of 16 subrecipients offering Title X services at 85 service sites. *Id.* at ¶4.
15 The Family Planning Program collaborates with other programs in the DOH, other
16 state agencies, subrecipient network organizations, and other family planning,
17 primary health care, and social service organizations to ensure that Title X
18 services are available statewide on issues related to women’s health, adolescent
19 health, family planning, sexually transmitted infection (STI) and Human
20 Immunodeficiency Virus (HIV) prevention and treatment, intimate partner
21 violence, and unintended pregnancy. *Id.*

22 NFPRHA represents more than 850 health care organizations in all 50
23 states, the District of Columbia and the U.S. territories, as well as individual
24 professional members with ties to family planning care. ECF No. 19 at ¶5.
25 NFPRHA currently has more than 65 Title X grantee members and almost 700
26 Title X subrecipient members. These NFPRHA member organizations operate or
27 fund a network of more than 3,500 health centers that provide family planning
28 services to more than 3.7 million Title X patients each year. *Id.* at ¶7.

1 The scope of the care provided by Title X programs is summarized in
2 OPA's current Program Requirements:

3 All Title X-funded projects are required to offer a broad range of
4 acceptable and effective medically (U.S. Food and Drug
5 Administration (FDA)) approved contraceptive methods and related
6 services on a voluntary and confidential basis. Title X services
7 include the delivery of related preventive health services, including
8 patient education and counseling; cervical and breast cancer
9 screening; sexually transmitted disease (STD) and human
10 immunodeficiency virus (HIV) prevention education, testing and
11 referral; and pregnancy diagnosis and counseling.

12 POA, *Program Requirements for Title X Funded Family Planning Projects*,
13 at 5 (Apr. 2014), [https://www.hhs.gov/opa/sites/default/files/Title-X-2014-
14 Program-Requirements.pdf](https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf) ("Program Requirements"). Title X projects also
15 provide basis infertility services, such as testing and counseling. 1:19-cv-
16 3045-SAB, ECF No. 1, at ¶43.

17 The Title X statute has always provided that "[n]one of the funds
18 appropriated under this subchapter shall be used in programs where abortion
19 is a method of family planning." 42 U.S.C. § 300a-6 ("Section 1008"). The
20 statute authorizes the Secretary to promulgate regulations governing the
21 program. 42 U.S.C. § 300a-4.

22 The Secretary adopted regulations in 1971 and they remained in
23 effect until 1988 when the Secretary adopted final regulations that
24 drastically altered the landscape in which Title X grantees operated. To
25 summarize, the 1988 regulations:

- 26 • Prohibited Title X projects from counseling or referring clients
27 for abortion as a method of family planning;
- 28 • Required grantees to separate their Title X project—physically
and financially—from prohibited abortion-related activities
- Established compliance standards for family planning projects
- Prohibited certain actions that promote, encourage, or advocate

1 abortion as method of family planning, such as using project funds for
2 lobbying for abortion, developing and disseminating materials
3 advocating abortion, or taking legal action to make abortion available
4 as a method of family planning.

5 Those regulations were challenged in federal courts and ultimately upheld
6 by the United States Supreme Court. *See Rust v. Sullivan*, 500 U.S. 173 (1991)⁴.
7 The 1988 rules were never fully implemented due to ongoing litigation and
8 bipartisan concern over its invasion of the medical provider-patient relation. State
9 of Washington, Complaint, ECF No. 1 at ¶30.

10 In 1993, President Clinton suspended the 1988 Regulations by way of
11 a Presidential memorandum to the Department:

12 Title X of the Public Health Services Act [this subchapter] provides
13 Federal funding for family planning clinics to provide services for
14 low-income patients. The Act specifies that Title X funds may not be
15 used for the performance of abortions, but places no restrictions on
16 the ability of clinics that receive Title X funds to provide abortion
17 counseling and referrals or to perform abortions using non-Title X
18 funds. During the first 18 years of the program, medical professionals
19 at Title X clinics provided complete, uncensored information,
20 including nondirective abortion counseling. In February 1988, the
Department of Health and Human Services adopted regulations,
which have become known as the “Gag Rule,” prohibiting Title X
recipients from providing their patients with information, counseling

21 ⁴ In *Rust*, the United States Supreme Court held that (1) the regulations were based
22 on permissible construction of the statute prohibiting the use of Title X funds in
23 programs in which abortion is a method of family planning; (2) the regulations do
24 not violate First Amendment free speech rights of Title X fund recipients, their
25 staffs or their patients by impermissibly imposing viewpoint-discriminatory
26 conditions on government subsidies; and (3) regulations do not violate a woman’s
27 Fifth Amendment right to choose whether to terminate a pregnancy and do not
28 impermissibly infringe on doctor-patient relationship. 500 U.S. at 184-203.

1 or referrals concerning abortion. Subsequent attempts by the Bush
2 Administration to modify the Gag Rule and ensuing litigation have
3 created confusion and uncertainty about the current legal status of the
4 regulations.

5 The Gag Rule endangers women’s lives and health by preventing
6 them from receiving complete and accurate medical information and
7 interferes with the doctor-patient relationship by prohibiting
8 information that medical professionals are otherwise ethically and
9 legally required to provide to their patients. Furthermore, the Gag
10 Rule contravenes the clear intent of a majority of the members of both
11 the United States Senate and House of Representatives, which twice
12 passed legislation to block the Gag Rule's enforcement but failed to
13 override Presidential vetoes.

14 For these reasons, you have informed me that you will suspend the
15 Gag Rule pending the promulgation of new regulations in accordance
16 with the “notice and comment” procedures of the Administrative
17 Procedure Act [5 U.S.C.A. §§ 551 et seq., 701 et seq.].

18 “The Title X Gag Rule,” Memorandum for the Secretary of Health and
19 Human Services, 1993 WL 366490 (Jan. 22, 1993).

20 New regulations were finalized in 2000, 65 Fed. Reg. 41270 (Jul. 3,
21 2000), *codified at* 42 C.F.R. Pt. 59, and these regulations remain in effect
22 unless and until the new Final Rule is implemented.

23 **Congressional Intent / The Department’s Program Requirements**

24 Plaintiffs argue that laws passed by Congress since *Rust* limit the
25 Department’s discretion in implementing Title X regulations. These laws include
26 Section 1554 of the ACA and congressional Non-directive Mandates contained in
27 appropriation bills. They also rely on the Department’s own program requirements
28 to support their arguments.

29 **1. § 1554 of the ACA**

30 Section 1554 of the ACA states:

31 Notwithstanding any other provision of this Act, the Secretary of Health and
32 Human Services shall not promulgate any regulation that--

- 1 (1) creates any unreasonable barriers to the ability of individuals to obtain
- 2 appropriate medical care;
- 3 (2) impedes timely access to health care services;
- 4 (3) interferes with communications regarding a full range of treatment
- 5 options between the patient and the provider;
- 6 (4) restricts the ability of health care providers to provide full disclosure of
- 7 all relevant information to patients making health care decisions;
- 8 (5) violates the principles of informed consent and the ethical standards of
- 9 health care professionals; or
- 10 (6) limits the availability of health care treatment for the full duration of a
- 11 patient's medical needs.

12 42 U.S.C. § 18114.

13 **2. Appropriations Mandate**

14 With the Non-directive Mandate, Congress has explicitly required every
15 year since 1996 that “all pregnancy counseling [in Title X projects] shall be
16 nondirective.” NFPRHA, *et al.* Complaint, 1:19-cv-3045-SAB, ECF No. 1, at ¶78.
17 Non-directive counseling provides the patient with all options relating to her
18 pregnancy, including abortion. *Id.* at ¶76. Congress has been providing Non-
19 directive Mandates in its appropriations bills for the past 24 years.

20 **3. Department of Health and Human Services Program**

21 **Requirements / Quality Family Planning**

22 Title X grantees are required to follow the Quality Family Planning (QFP)
23 guidelines, issued by the Centers for Disease Control and Prevention and OPA.
24 State of Washington, Complaint, ECF No. 1, at ¶45. This document reflects
25 evidence-based best practices for providing quality family planning services in the
26 United States.⁵ It requires that options counseling should be provided to pregnant

27 ⁵ “Providing Quality Family Planning Services: Recommendations of CDC and the
28 U.S. Office of Population Affairs,” *Morbidity and Mortality Weekly Report* Vol.
62, No. 4 (April 25, 2014), *available at* <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf> (last
accessed April 24, 2019) (the QFP).

1 patients as recommended by the American College of Obstetricians and
2 Gynecologists and others, including that patients with unwanted pregnancy should
3 be “fully informed in a balanced manner about all options, including raising the
4 child herself, placing the child for adoption, and abortion.” *Id.* at ¶46.

5 The Department’s Program Requirements require Title X projects to provide
6 nondirective pregnancy counseling. *Id.* at ¶44.

7 **Federal Conscience Laws**

8 In the Executive Summary of the Final Rule, the Department indicates that
9 one of the purposes of revising the Title X regulations was to eliminate provisions
10 which are inconsistent with the health care conscience statutory provisions. 84
11 Fed. Reg. 7714, 7716. These provisions include the Church Amendment, the
12 Coats-Snowe Amendment and the Weldon Amendment. *Id.*

13 **1. The Church Amendment**

14 “The Church Amendments, among other things, prohibit certain HHS
15 grantees from discriminating in the employment of, or the extension of staff
16 privileges to, any health care professional because they refused, because of their
17 religious beliefs or moral convictions, to perform or assist in the performance of
18 any lawful sterilization or abortion procedures. The Church Amendments also
19 prohibit individuals from being required to perform or assist in the performance of
20 any health service program or research activity funded in whole or in part under a
21 program administered by the Secretary contrary to their religious beliefs or moral
22 convictions. *See* 42 U.S.C. 300a-7.” 84 Fed. Reg. at 7716, n.7.

23 **2. 1996 Coats-Snowe Amendment**

24 “The Coats-Snowe Amendment bars the federal government and any State
25 or local government that receives federal financial assistance from discriminating
26 against a health care entity, as that term is defined in the Amendment, who refuses,
27 among other things, to provide referrals for induced abortions. *See* 42 U.S.C.
28 238n(a).” 84 Fed. Reg. at 7716, n.8.

3. 2005 Weldon Amendment

“The Weldon Amendment was added to the annual 2005 health spending bill and has been included in subsequent appropriations bills.” 84 Fed. Reg. at 7716, n. 9. “The Weldon Amendment bars the use of appropriated funds on a federal agency or programs, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not, among other things, refer for abortions.” *Id.*

Analysis

As set forth above, the Ninth Circuit uses a sliding scale approach in determining whether it is appropriate to grant a preliminary injunction. Although Plaintiffs have met their burden of showing that all four factors tip in their favor, the irreparable harm and balance of equities factors tip so strongly in Plaintiffs’ favor that a strong showing of likelihood on the merits was not necessary.

1. Likelihood of Success on the Merits

Plaintiffs have presented reasonable arguments that indicate they are likely to succeed on the merits, thus meeting the threshold inquiry. In so finding, the Court has not concluded that Plaintiffs will definitely prevail on the merits, nor has it concluded that they are more likely going to prevail. The preliminary injunction standard requires neither of these conclusions. *See Azar*, 911 F.3d at 582 (“The purpose of such interim equitable relief is not to conclusively determine the rights of the parties but to balance the equities as the litigation moves forward.”) (quoting *Trump v. Int’l Refugee Assistance Proj.*, ___ U.S. ___, 137 S.Ct. 2080, 2087 (2017)). Rather, it requires a determination that Plaintiff has made a colorable claim—a claim that has merit and a likely chance of success.

First, Plaintiffs have presented initial facts and argument that the separation requirement in the Final Rule forces clinics that provide abortion services to maintain separate facilities and finances for Title X programs will more likely than

1 not increase their expenses unnecessarily and unreasonably.

2 Second, Plaintiffs have presented initial facts and argument that the Final
3 Rule gag requirement would be inconsistent with ethical, comprehensive, and
4 evidence-based health care.

5 Third, Plaintiffs have presented initial facts and argument that the Final
6 Rule violates Title X regulations, the Non-directive Mandates and Section 1554 of
7 the Affordable Care Act and is also arbitrary and capricious.

8 Specifically, Plaintiffs have demonstrated the Final Rule likely violates the
9 central purpose of Title X, which is to equalize access to comprehensive,
10 evidence-based, and voluntary family planning. They have presented facts and
11 argument that the Final Rule violates the Non-directive Mandate because it
12 requires all pregnant patients to receive referrals for pre-natal care, regardless of
13 whether the patient wants to continue the pregnancy, and regardless of the best
14 medical advice and treatment that might be recommended for that patient.

15 They have also presented facts and argument that the Final Rule likely
16 violates Section 1554 of the ACA because the Final Rule creates unreasonable
17 barriers for patients to obtain appropriate medical care; impedes timely access to
18 health care services; interferes with communications regarding a full range of
19 treatment options between the patient and the health care provider, restricts the
20 ability of health care providers to provide full disclosure of all relevant
21 information to patients making health care decisions, and violates the principles of
22 informed consent and the ethical standards of health care professions.

23 Fourth, Plaintiffs, with the help from *Amicus* parties, have presented facts
24 and argument that the Final Rule is arbitrary and capricious because it reverses
25 long-standing positions of the Department without proper consideration of sound
26 medical opinions and the economic and non-economic consequences.

27 Finally, Plaintiffs have presented facts and argument that the Department
28 failed to consider important factors, acted counter to and in disregard of the

1 evidence in the administrative record and offered no reasoned analysis based on
2 the record. Rather, it seems the Department has relied on the record made 30 years
3 ago, but not the record made in 2018-19.

4 **2. Irreparable Harm**

5 Plaintiffs have demonstrated they are likely to suffer irreparable harm in the
6 absence of a preliminary injunction by presenting facts and argument that the Final
7 Rule may or likely will: (1) seriously disrupt or destroy the existing network of
8 Title X providers in both the State of Washington and throughout the entire
9 nation—this network has been carefully knit together over the past 45 years and
10 there is no evidence presented by the Department that Title X is being violated or
11 ignored by this network of providers; (2) impose additional and unnecessary costs
12 on the State of Washington and other states; (3) harm the health of the patients
13 who rely on the existing Title X providers; and (4) drive many Title X providers
14 from the system either because of the increased costs imposed by the new
15 separation requirements or because they cannot or will not comply with the
16 allegedly unprofessional gag rule requirements.

17 Washington State has shown that it is not legally or logistically feasible for
18 Washington to continue accepting any Title X funding subject to the Final Rule.
19 At the minimum, Washington stands to lose more than \$28 million in savings from
20 the loss of federal dollars. It has demonstrated the harmful consequences of the
21 Final Rule will uniquely impact rural and uninsured patients. If the Final Rule is
22 implemented, over half of Washington counties would be unserved by a Title X-
23 funded family planning provider. Students at Washington colleges and universities
24 will be especially hurt by the Final Rule. DOH reports it does not have the funding
25 that would be required to comply with the Final Rule, nor would it be able to
26 comply with the May 3, 2019 deadline.

27 NFPRHA currently has more than 65 Title X grantee members and almost
28 700 Title X sub-recipient members. These NFPRHA member organizations

1 operate or fund a network of more than 3,500 health centers that provide family
2 planning services to more than 3.7 million Title X patients each year. NFPRHA
3 has shown that upon its effective date, the Final Rule will cause all current
4 NFPRHA members grantees, sub-recipients, and their individual Title X clinicians
5 to face a Hobson's Choice that harms patients as well as the providers. Faced with
6 this difficult choice, many NFPRHA members will leave the network once the
7 Final Rule becomes effective, thereby leaving low-income individuals without
8 Title X providers.

9 It is worth noting that Plaintiffs have submitted substantial evidence of
10 harm, including declarations from Karl Eastlund, President and CEO of Planned
11 Parenthood of Greater Washington and North Idaho, ECF No. 10; Cynthia Harris,
12 program manager for the Family Planning Program, Washington DOH, ECF No.
13 11; Anuj Khattar, M.D., primary care physician and reproductive health provider,
14 ECF No. 12; Dr. Judy Kimelman, practitioner at Seattle Obstetrics & Gynecology
15 Group, ECF No. 13; Bob Marsalli, CEO of the Washington Association for
16 Community Health, ECF No. 14; David Schumacher, Director of the Office of
17 Financial Management, State of Washington, ECF No. 15; Dr. Judy Zerzan-Thul,
18 Chief Medical Officer for the Washington State Health Care Authority, ECF No.
19 16; Clare M. Coleman, President and CEO of the National Family Planning &
20 Reproductive Health Association, ECF No. 19; Dr. Kathryn Kost, Acting Vice
21 President of Domestic Research at the Guttmacher Institute, ECF No. 20; Connie
22 Cantrell, Executive Director of the Feminist Women's Health Center, ECF No. 21;
23 Kristin A. Adams, Ph.D, President and CEO of the Indiana Family Health Council,
24 ECF No. 22; J. Elisabeth Kruse, M.S., C.N.M., A.R.N.P, Lead Clinician for Sexual
25 and Reproductive Health and Family Planning at the Public Health Department for
26 Seattle and King County, Washington, ECF No. 23; Tessa Madden, M.D., M.P.H.,
27 Director of the Family Planning Division, Department of Obstetrics and
28 Gynecology, Washington University School of Medicine, ECF No. 24; Heather

1 Maisen, Manager of the Family Planning Program in the Public Health
2 Department for Seattle and King County, Washington, ECF No. 25; and Sarah
3 Prager, M.D., Title X Director of the Feminist Women’s Health Center, ECF No.
4 26.

5 Yet, the Government’s response in this case is dismissive, speculative, and
6 not based on any evidence presented in the record before this Court.

7 **3. Balance of Equities/Public Interest**

8 The balance of equities and the public interest strongly favors a preliminary
9 injunction, which tips the scale sharply in favor of Plaintiffs.

10 There is no public interest in the perpetration of unlawful agency action.
11 Preserving the status quo will not harm the Government and delaying the effective
12 date of the Final Rule will cost it nothing. There is no hurry for the Final Rule to
13 become effective and the effective date of May 3, 2019 is arbitrary and
14 unnecessary.

15 On the other hand, there is substantial equity and public interest in
16 continuing the existing structure and network of health care providers, which
17 carefully balances the Title X, the congressional Non-directive Mandates, and
18 Section 1554 of the Affordable Care Act, while the legality of the new Final Rule
19 is reviewed and decided by the Court.

20 Accordingly, **IT IS HEREBY ORDERED:**

21 1. The State of Washington’s Motion for Preliminary Injunction, ECF
22 No. 9, is **GRANTED**.

23 2. National Family Planning & Reproductive Health Center, *et al.*’s
24 Motion for Preliminary Injunction, ECF No. 18, is **GRANTED**.

25 3. Defendants and their officers, agents, servants, employees, and
26 attorneys, and any person in active concert or participation with them, are
27 **ENJOINED** from implementing or enforcing the Final Rule entitled *Compliance*
28 *with Statutory Program Integrity Requirements*, 84 Fed. Reg. 7714-01 (March 4,

1 2019), in any manner or in any respect, and shall preserve the status quo pursuant
2 to regulations under 42 C.F.R., Pt. 59 in effect as of the date of April 24, 2019,
3 until further order of the Court.

4 4. No bond shall be required pursuant to Fed. R. Civ. P. 65(c).

5 **IT IS SO ORDERED.** The Clerk of Court is directed to enter this Order
6 and forward copies to counsel.

7 **DATED** this 25th day of April 2019.



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A handwritten signature in blue ink that reads "Stanley A. Bastian".

15 Stanley A. Bastian
16 United States District Judge
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