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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE**

THE FAMILY PLANNING ASSOCIATION
OF MAINE D/B/A MAINE FAMILY
PLANNING, on behalf of itself, its staff, and its
patients;

and

J. DOE, DO, MPH, individually and on behalf of
Dr. Doe's patients,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES;

ALEX M. AZAR II, in his official capacity as
Secretary of Health and Human Services;

OFFICE OF POPULATION AFFAIRS;

and

DIANE FOLEY, M.D., in her official capacity
as the Deputy Assistant Secretary for Population
Affairs,

Defendants.

Case No.1:19-cv-00100-LEW

BRIEF OF AMICUS CURIAE POLICY
INTEGRITY IN SUPPORT OF
PLAINTIFFS' MOTION FOR
PRELIMINARY INJUNCTION

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Dep’t of Health and Human Services, *Guidelines for Regulatory Impact Analysis: A Primer* (2016),
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Office of Mgmt. & Budget, *Circular A-4* (2003),
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Revesz, Richard & Michael Livermore, *Retaking Rationality: How Cost-Benefit Analysis Can Better Protect the Environment and Our Health* (2008) 1, 6

Schwartz, Jason “Approaches to Cost-Benefit Analysis” in the *Handbook of Regulatory Impact Assessment* (Claire A. Dunlop & Claudio M. Radaelli eds., 2016) 1, 13

The Institute for Policy Integrity at New York University School of Law (“Policy Integrity”)¹ submits this brief as *amicus curiae* in support of Plaintiffs’ motions for preliminary injunction of Defendants’ final rule, Compliance with Statutory Program Integrity Requirements, 84 Fed. Reg. 7714 (Mar. 4, 2019) (“the Rule”).

INTERESTS OF AMICUS CURIAE

Policy Integrity is a nonpartisan, not-for-profit think tank dedicated to improving the quality of government decision-making through advocacy and scholarship in the fields of administrative law, economics, and public policy. Policy Integrity’s legal and economic experts have produced extensive scholarship on the best practices for regulatory impact analysis and the proper valuation of regulatory costs and benefits. Our director, Richard L. Revesz, has published more than eighty articles and books on environmental and administrative law, including on the legal and economic principles for rational regulatory decisions. *See e.g.*, Richard Revesz & Michael Livermore, *Retaking Rationality: How Cost-Benefit Analysis Can Better Protect the Environment and Our Health* (2008).² Our legal director, Jason A. Schwartz, has similarly produced expert scholarship on regulatory decision-making, including the book chapter, “Approaches to Cost-Benefit Analysis” in the *Handbook of Regulatory Impact Assessment* (Claire A. Dunlop & Claudio M. Radaelli eds., 2016).

Policy Integrity has filed many *amicus curiae* briefs advising courts on agencies’ economic analyses of regulatory actions. *See e.g.*, Br. for Inst. for Policy Integrity as Amicus

¹ This brief does not purport to represent the views of New York University School of Law, if any. Policy Integrity states that no party’s counsel authored this brief in whole or in part, and no party or party’s counsel contributed money intended to fund the preparation or submission of this brief. No person—other than the *amicus curiae*, its members, or its counsel—contributed money intended to fund the preparation or submission of this brief.

² A full list of publications is available on Professor Revesz’s online faculty profile, <https://its.law.nyu.edu/facultyprofiles/index.cfm?fuseaction=profile.overview&personid=20228>.

Curiae, California v. U.S. Bureau of Land Mgmt., 277 F. Supp. 3d 1106 (N.D. Cal. 2017) (arguing that failure to consider forgone benefits is arbitrary); *see California*, 277 F. Supp. 3d at 1123 (ruling that failure to consider the forgone benefits was arbitrary).

Policy Integrity has particular expertise on the regulatory impact analysis that the Department of Health and Human Services (HHS) conducted in support of its rulemaking on the obligations of Title X grantees. We both submitted comments on the proposed rule, Policy Integrity Comment Ltr. (Aug. 1, 2018)³, and formally met with the Office of Information and Regulatory Affairs to present critiques of the regulatory impact analysis. Policy Integrity seeks to provide this court with context on the legal and economic standards for best practices in regulatory impact analysis, which will show that HHS’s analysis of the Rule’s costs and benefits arbitrarily violated those standards. Policy Integrity therefore files the following brief in support of the Plaintiffs’ motions for preliminary injunction.

SUMMARY OF ARGUMENT

Plaintiffs’ motions for preliminary injunction argue that the Rule is arbitrary and capricious because HHS failed to assess the Rule’s substantial health costs, grossly underestimated and ignored compliance costs, and made conclusory statements about the Rule’s alleged benefits without evidentiary support. *E.g.*, Mem. Supp. Mot. Prelim. Inj. 22-31, ECF No. 17) (“Family Planning Mem.”). This amicus memorandum provides this Court with context on the legal standards for reviewing regulatory impact analyses and the economic standards for conducting regulatory impact analyses—including HHS’s own guidelines on best practices for assessing costs and benefits. The Rule’s regulatory impact analysis thoroughly flunks those standards, and HHS’s justification for the Rule is therefore arbitrary.

³ Hyperlinks to comments are available in the Table of Authorities, *supra*.

HHS's justification for the Rule enumerates a few highly speculative benefits while simultaneously disregarding several important categories of significant costs highlighted by commenters. Both the conclusory pronouncement of benefits and the outright dismissal of probable costs lack the reasoned explanation required under the Administrative Procedure Act and violate clear instructions from both the Office of Management and Budget's *Circular A-4 on Regulatory Analysis* and HHS's *Guidelines for Regulatory Impact Analysis*.

Courts have made clear that agencies must reasonably consider all important regulatory costs, including any significant direct or indirect health costs. Yet HHS unreasonably concludes that the Rule will impose no costs on public health or patient wellbeing, despite ample evidence in the record to the contrary, and despite clear guidelines on the need to quantitatively assess such health costs to the fullest extent practicable.

Similarly, the Rule significantly underestimates the direct costs of compliance, contrary to both common sense and evidence in the record indicating these costs will be larger by an order of magnitude. HHS cites no market data, literature, economic models, grantee interviews, or any other source or methodology to support its gross underestimates.

Finally, HHS fails to provide any evidence to support many of its claimed expected benefits of the Rule, including a predicted net reduction in unwanted pregnancies and "enhanced compliance" with Title X's prohibition on the use of funds for abortion services.

By ignoring best practices and plucking from thin air its estimates of costs and benefits, HHS relies on a flawed justification of the Rule, rendering its decision-making arbitrary.

ARGUMENT

Final agency actions, like the Rule, are arbitrary and capricious under the Administrative Procedure Act, 5 U.S.C. § 706(2), if an agency failed to "examine the relevant data," "consider

an important aspect of the problem,” or “articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted). “Important aspects” of the Rule include its costs and benefits because, as the Supreme Court has made clear, “reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions.” *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (emphasis in original). In weighing regulatory actions, agencies cannot “put a thumb on the scale” by undervaluing key effects and overvaluing others. *Ctr. for Biological Diversity v. Nat’l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008); *see also California v. BLM*, 277 F. Supp. 3d 1106, 1123 (N.D. Cal. 2017) (agencies impermissibly considered only “one side of the equation” by calculating benefits and ignoring costs).

Regulatory impact analyses can reveal to courts whether an agency ignored an “important aspect” of the rule’s costs or benefits, failed to examine “relevant data” from the record on the rule’s costs or benefits, or otherwise irrationally based its regulatory choices on arbitrary analysis. *See Nat’l Ass’n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012); *id.* at 1036 (“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.”).

Agencies conduct regulatory impact analyses under Executive Order 12,866. 58 Fed. Reg. 51,735 (Oct. 4, 1993). Pursuant to Executive Order 12,866, the Office of Management and Budget classified the Rule as a “significant regulatory action,” requiring a thorough regulatory impact analysis. *See* 84 Fed. Reg. at 7775-76. Indeed, any regulation that, like the Rule, “materially alters the . . . obligations” of federal grantees is a “significant” action. Exec. Order No. 12,866 § 3(f)(3); *see also* Policy Integrity Comment Ltr. 2. Executive Order 12,866 directs

agencies to “assess both the costs and the benefits of the intended regulation and . . . adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.” Exec. Order 12,866 § 1(b)(6). The Office of Management and Budget under President George W. Bush issued *Circular A-4 on Regulatory Analysis*, to “standardiz[e] the way benefits and costs of Federal regulatory actions are measured.” Office of Mgmt. & Budget, *Circular A-4* at 1 (2003) [hereinafter *Circular A-4*]. HHS has also published its own internal guidelines for best practices. HHS, *Guidelines for Regulatory Impact Analysis* (2016) [hereinafter HHS, *Guidelines*]. Both *Circular A-4* and HHS’s *Guidelines* detail the best economic practices for gathering data, making reasonable assumptions, assessing costs and benefits, and comparing overall regulatory impacts.

In particular, *Circular A-4* and HHS’s *Guidelines* explain that direct and indirect health costs must be accounted for and quantified to the fullest extent practicable; that estimates of direct compliance costs should be based on surveys, literature reviews, and other reliable sources and reasonable assumptions; and that benefits should be quantified to the fullest extent practicable and based on reasonable estimates. As detailed in the next three sections, the Rule’s impact analysis violates all these standards for best practices and ignores both “important aspects of the problem” and “relevant data,” *State Farm*, 463 U.S. at 43, and consequently HHS has arbitrarily and capriciously violated the requirements of the Administrative Procedure Act.

I. HHS’s Failure to Assess the Rule’s Significant Health Costs Violated Best Practices for Regulatory Impact Analysis and Was Arbitrary And Capricious

Courts have made clear that agencies must reasonably consider the important costs of their rules, including any significant direct or indirect health costs. In *Michigan v. EPA*, the Supreme Court ruled that “‘cost’ includes more than the expense of complying with regulations” and that “any disadvantage could be termed a cost.” 135 S. Ct. 2699, 2707 (2015). In fact, the

Supreme Court highlighted that it would generally be irrational not to consider the “harms that regulation might do to human health.” *Id.* Other courts have similarly long required agencies to assess all important regulatory costs to health, safety, and welfare, whether the costs are direct or indirect. *E.g.*, *Competitive Enter. Inst. v. Nat’l Highway Traffic Safety Admin.*, 956 F.2d 321, 326-27 (D.C. Cir. 1992) (remanding a fuel-efficiency rule due to the agency’s failure to acknowledge indirect safety costs); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1225 (5th Cir. 1991) (striking down a rule banning asbestos for failure to consider the indirect safety effects of substitute, asbestos-free car brakes being less effective).

Proper consideration of direct and indirect effects is a crucial part of any regulatory impact analysis. *See Revesz & Livermore, Retaking Rationality, supra*, at 57-58. Executive Order 12,866 requires agencies to consider not just “direct cost . . . to businesses and others in complying with the regulation,” but also “any adverse effects” the rule might have on “the efficient functioning of the economy, private markets . . . health, safety, and the natural environment.” Exec. Order No. 12,866 § 6(a)(3)(C)(ii). Longstanding guidance on regulatory impact analysis from the Office of Management and Budget similarly instructs agencies to “look beyond the direct benefits and direct costs of [their] rulemaking and consider any important ancillary [i.e., indirect] benefits and countervailing risks.” *Circular A-4* at 26. Furthermore, agencies must try to the extent “feasible” to “quantify and monetize ancillary benefits and countervailing risks,” and “[t]he same standards of information and analysis quality that apply to direct benefits and costs should be applied” to indirect effects as well. *Id.*; *see also* HHS, *Guidelines* at 43 (requiring HHS to “quantify[] impacts to the greatest extent possible”).

Despite these requirements to assess all important costs, HHS’s regulatory impact analysis focuses instead almost exclusively on the direct costs of compliance, like the paperwork

costs of additional documentation and learning the rule. 84 Fed. Reg. 7714, 7777-82 (spending six pages on costs like training and documenting compliance). In contrast, the Rule spends a mere two paragraphs responding to commenters' extensive documentation of the significant probable impacts to the health of patients, *Id.* at 7775, before later assuming without any quantitative analysis that the "net impact" to patients "will be zero," *Id.* at 7782. In reaching this conclusion, there is no evidence that HHS consulted any data on the health outcomes of Title X patients, conducted any interviews with Title X grantees or patients, ran any models, seriously considered the data from public comments, or otherwise attempted in any meaningful way to quantify any of the likely impacts to patients, such as lost access to care, increased pregnancies, and transaction costs. The likely impacts to patients are discussed in the following subsections.

A. The Rule Will Inevitably and Detrimentially Affect Patients' Health

To understand the categories and magnitude of health costs that HHS failed to properly consider, it is useful to understand grantees' and providers' potential responses to the Rule. The Rule's Separation Requirement forces clinics that provide abortion services to maintain separate facilities and finances for their Title X programs, a requirement that would undoubtedly increase their expenses. Additionally, many Title X recipients, including Plaintiffs, assert that compliance with the Rule's Gag Requirement would be inconsistent with ethical and professional principles, and indicate that many providers will respond by dropping out of the program rather than violate these standards.

Therefore, affected entities may choose to respond to the Rule in a handful of ways:

- (1) Comply with the rule and incur the additional costs of the Separation Requirement;
- (2) Forgo Title X funding;
- (3) Cease to provide abortion services or abortion counseling; and/or

(4) Close due to the requirements of the Rule.

In the first two of these scenarios, it is likely that family planning and reproductive health services become costlier for patients. Their care providers must raise costs to either meet the Separation Requirement (e.g., to establish new facilities and hire new staff) or to replace lost federal funding. In the third response scenario, women lose access to legal, safe, and affordable abortion services and to information about their options. In the final scenario, patients must go elsewhere to receive the reproductive healthcare and family planning services that they have come to rely on. In all scenarios, the end result is that some patients will lose access to some critical healthcare services, and that loss of access will result in a number of very real health, financial, physical, and psychological consequences for patients and their families.

These likely scenarios implicate at least three categories of costs that were either dismissed without reasoned explanation or ignored entirely by the agency. These costs are: (i) the health costs arising from lack of access to healthcare providers; (ii) the likely increase in unwanted pregnancies and births; and (iii) the transaction costs imposed on patients searching for new providers. Each of these costs is ignored in the Rule, which instead asserts that there are *no* costs beyond quantified compliance costs. 84 Fed. Reg. at 7777, Table 1 (listing “Non-quantified Costs: None”).

B. Patients Will Experience Significant Costs from Lost Access to Healthcare

Numerous commenters supplied HHS with arguments and evidence that the changes in the Title X program brought about by the Rule would adversely affect patient health. Title X grantees provide a wide range of services beyond the provision of contraceptives, including “conducting screening for cervical cancer, diabetes, high blood pressure, and sexually transmitted diseases,” and, as pointed out by a public health expert in comments, these Title X-

provided services are often low-income women's "only interaction with the health care system at all." Claire Brindis, DrPH Comment Ltr. 3 (July 31, 2018). If these providers close their doors or raise their costs as a result of the Rule, some patients will be left without a meaningful alternative, incurring substantial health costs. As Plaintiffs point out, many Title X recipients operate in rural areas where their patients have scarce access to substitute healthcare providers. Family Planning Mem. 13, 17, 27, 34-35, 39; *see also* Planned Parenthood Comment Ltr. 15-16, 70 (July 31, 2018). These closures will result in undesirable health outcomes, such as the spike in HIV that occurred when Planned Parenthood was forced to close a rural clinic in Indiana. Brindis Comment Ltr. 6-7. These negative health effects weigh against the Rule, and the agency must acknowledge and account for them. HHS's own guidelines for conducting regulatory impact analyses emphasize that "reductions in government payments" to healthcare providers may affect patient access and treatments, "in turn affecting health outcomes," and that these changes "should be addressed in the benefit-cost analysis." HHS, *Guidelines* at 23. HHS arbitrarily and capriciously failed to do so in the Rule.

C. Patients Will Experience Significant Costs from Increased Unintended Pregnancies and Births

Although HHS acknowledges that it expects some Title X grantees to exit the program in response to the Rule, the agency argues that lost grantees will be replaced by new grantees entering the program, with no net costs to the patient population. However, the agency provides no evidence to support its claim that an equal number providers will enter the program as exit, 84 Fed. Reg. at 7782, or the assumption that new providers will be able to cover the same large patient population that existing providers previously served. Further, the Rule specifically intends to open up Title X funding to providers who offer only a limited range of family planning methods, including only natural planning and abstinence counseling (as opposed to

traditional contraception). *Id.* at 7741. Therefore, these hypothetical new grantees are unlikely to serve as perfect substitutes for those providers that currently provide a full range of services but may be forced to exit the program in response to the Rule.⁴ The only rational conclusion is that some number of patients will lose access to contraceptive services they have come to rely on. HHS, however, argues that enabling Title X funding to support clinics that provide only natural planning methods will, in fact, “decrease unintended pregnancies, not increase them, because clients are more likely to visit clinics that respect their views and beliefs.” *Id.* at 7743. The agency provides no evidence or quantitative analysis to estimate how many women, if any, currently decline to seek Title X care because of their personal beliefs. Nor does the agency provide any quantitative assessment of whether this body of women outweighs the sizable number that will lose access to the services they currently receive under Title X. Quantifying effects serves as an important tool to help agencies “appropriately balance” a regulation’s competing costs and risk reductions, *see* HHS, *Guidelines* at 47, yet HHS disregards its own *Guidelines* in order to reach its arbitrary conclusion.

HHS’s assertion that clinic closures will not result in an increase in unwanted pregnancies runs counter to the substantial weight of record evidence. In response to the proposed rule, expert commenters highlighted that public funding of family planning services has averted millions of unintended pregnancies each year, resulting in significant avoided costs related to child health care and maternity. Brindis Comment Ltr. 12. HHS’s assertion that “[c]ommenters offer no compelling evidence that this rule will increase unintended pregnancies or decrease access to contraception,” 84 Fed. Reg. at 7785, is at odds with record evidence to the

⁴ Indeed, one of the newest recipients of Title X grant funding announced recently that five of its seven clinics will provide no contraceptives. Jessie Hellman, *Trump Administration Awards \$1.7 Million Family Planning Grant to Anti-Abortion Clinics*, The Hill, Mar. 29, 2019.

contrary, including the fact that Texas's cuts to family-planning funding resulted in a substantial decrease in use of effective birth control and increase in births. Brindis Comment Ltr. 12; *see also* Am. Acad. of Nursing, Comment Ltr. 2-3 (July 31, 2018). Even if HHS could not fully quantify the health costs from clinic closures, the agency minimally should have attempted to quantify "counts" of "the number of organizations . . . [or] individuals affected," or otherwise used all the data provided by commenters as "indicators of potential costs or benefits." HHS, *Guidelines* at 48. Instead, and contrary to the requirements of the Administrative Procedure Act, HHS ignored commenters' data while failing to provide any reasoned explanation on why this evidence is not "compelling." *See McDonnell Douglas Corp. v. U.S. Dep't of the Air Force*, 375 F.3d 1182, 1187 (D.C. Cir. 2004) (holding that "conclusory or unsupported suppositions" fail to satisfy the requirements of reasoned decision-making).

D. Patients Will Experience Significant Transaction Costs

HHS acknowledges that it expects some healthcare facilities to cease providing Title X services as a result of the Rule, but nevertheless predicts that "the net impact on those seeking services from current grantees will be zero," as new grantees will apply for participation in the program, replacing those that have exited, and "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." 84 Fed. Reg. at 7782. This analysis assumes perfect and immediate replacement of exiting grantees with entering grantees, and ignores any significant costs incurred by patients during inevitable transition gaps and delays. It also ignores that new grantees are, according to the very intention of the Rule itself, likely to provide a more limited range of services than existing grantees. Further, the analysis ignores the costs incurred by patients in seeking out these new services as well as the emotional costs of having lost a

familiar healthcare provider. *See* HHS, *Guidelines* at 26-28, 30-32 (detailing how to quantify the costs of time and travel). Finally, for those current Title X-funded facilities that do not close and instead choose to comply with the Separation Requirement, the Rule's compliance requirements may also make it more difficult for patients to access care at these service sites: for example, if sites change their phone numbers, email addresses, websites, and entrances in order to comply, 84 Fed. Reg. at 7789, patients may have difficulty finding and accessing care even at service sites previously familiar to them.

E. HHS Cannot Ignore Costs Even If They Are Uncertain or Difficult to Quantify

HHS attempts to justify its choice to ignore the costs of an increase in unintended pregnancies and births by arguing that “the Department is not aware... of actual data that could demonstrate a causal connection between the [Rule] 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.” *Id.* at 7775. Therefore, the Department concluded that these costs “are not likely or calculable impacts.” *Id.* In other words, just because indirect health costs are hard to quantify, HHS assumes that the costs are “not likely” or are “None.” *Id.* at 7777, Table 1 (listing “Non-quantified Costs: None”).

However, HHS cannot rationally ignore costs even if they are unquantified. “The mere fact that the magnitude of [an effect] is *uncertain* is no justification for *disregarding* the effect entirely.” *Public Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1219 (D.C. Cir. 2004) (emphasis in original). Stated differently, HHS has no license to ignore the effects of its decisions just because they are “difficult, if not impossible, to quantify reliably.” *Am. Trucking Assocs., Inc. v. EPA*, 175 F.3d 1027, 1052 (D.C. Cir. 1999), *rev'd on other grounds sub nom. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001). Executive Order 12,866 also makes clear

that it is “essential to consider” the “qualitative measures of costs and benefits that are difficult to quantify.” Exec. Order No. 12,866 § 1(a). HHS’s own guidelines on regulatory analysis contain an entire chapter on the importance of, and approaches for, meaningfully considering nonquantified effects. *See* HHS, *Guidelines* at 47-51; *id.* at 47 (“Ignoring potentially important nonquantified effects may lead to poor decisions.”); *compare* HHS, *Guidelines* at 51 (providing that “[a]t minimum” agencies “should list significant nonquantified effects in a table and discuss them qualitatively”), *with* 84 Fed. Reg. at 7777, Table 1 (listing “Non-quantified Costs: None”).

Indeed, HHS’s lack of consideration of difficult-to-quantify health costs is even more egregious when compared to the agency’s willingness to enumerate a long list of the Rule’s alleged benefits, each of which are unquantified, and many of which lack any evidentiary support at all, even of an anecdotal nature. *See infra* Section III.

II. HHS Arbitrarily Ignored Both Its Own Guidelines and Record Evidence and Grossly Underestimated Compliance Costs

Because the costs of complying with regulations often can be directly estimated from market data, assessing compliance costs is typically a straightforward part of agencies’ regulatory impact analyses. *See* Schwartz, *supra*, in *Handbook of Regulatory Impact Assessment* at 38 (“Many costs and some benefits will already be expressed in monetary terms, like prices of compliance equipment.”); *see also* *Circular A-4* at 21 (“Economists ordinarily consider market prices as the most accurate measure of the marginal value of goods and services to society.”).

HHS’s *Guidelines* on conducting cost-benefit analysis clearly direct how to evaluate capital and operating compliance costs: “1. Use market data to estimate the price of purchasing and installing equipment required by the regulation. . . . 2. Use market data to value the annual costs of labor, utilities, and other resources required for production, service provision, and the operation and maintenance of capital equipment.” HHS, *Guidelines for Regulatory Impact*

Analysis: A Primer at 8 (2016). The *Guidelines* elaborate that such market data “may be obtained through interviews, literature reviews, review of online merchandise catalogues, or other sources.” HHS, *Guidelines* at 32.

Yet in calculating the Rule’s direct compliance costs, there is no evidence that HHS followed its own guidelines or conducted any interviews of grantees, consulted any literature or market price data, ran any cost models, or even seriously considered public comments. For example, under the Separation Requirement, healthcare clinics that currently provide both Title X services and abortion services—including abortion referrals—must physically alter their facilities to create separate “treatment, consultation, examination and waiting rooms” and “office entrances and exits,” 84 Fed. Reg. at 7789. In the proposed rule, HHS estimated—without any reference to any evidence, methodology, or assumptions to support the numbers—that it would cost “an average of between \$10,000 and \$30,000, with a central estimate of \$20,000” in one-time expenses for facilities to comply with the Separation Requirement. 83 Fed. Reg. 25,502, 25,525. Those estimates were seemingly derived from thin air, in stark contrast to HHS’s own best practices for estimating costs. For example, when HHS has issued rules affecting Head Start grantees, its regulatory impact analyses rely on “internal datasets” based on grantees’ budgetary data and comprehensive surveys of grantees. *See* 81 Fed. Reg. 61,293, 61,375. By contrast, there is no indication that HHS talked to any Title X grantees about their likely costs before finalizing this Rule. That omission is particularly troubling because, under the longstanding Executive Order on regulatory impact analysis, proposed rules that “materially alter the . . . obligations of recipients” of federal grants are deemed to be “significant regulatory action[s],” Exec. Order 12,866 § 3(f)(3), and agencies must detail “the potential costs and benefits” of such actions, *id.* § 6(a)(3)(B)(ii).

Multiple Title X grantees (the regulated entities subject to the Rule's compliance costs) submitted detailed comments in response to the proposed rule that indicated their own capital costs of renovation and construction would be much higher, based on third-party reports and grantees' historical experiences. *See, e.g.*, Planned Parenthood Comment Ltr. 32 (estimating capital costs of \$625,000 per affected service site); Essential Access Health Comment Ltr. 13 (Aug. 1, 2018) (arguing that HHS's compliance cost estimates are "unrealistically low, and could feasibly amount to hundreds of thousands of dollars); Nat'l. Family Planning & Reproductive Health Ass'n. Comment Ltr. 37 (July 31, 2018) (estimating cost per site of at least \$300,000). Not only was HHS's estimate of one-time capital costs drastically off from grantees' own estimates by hundreds of thousands of dollars per site, but public comments also pointed out that HHS completely ignored ongoing costs for the additional staff and contracts for goods and services to operate the separate facilities. *See, e.g.*, Planned Parenthood Comment Ltr. 32-33. Plaintiff Maine Family Planning estimates that its own compliance with the Separation Rule would cost at least \$100,000 at its Augusta site, "with a new building costing potentially over \$500,000." Family Planning Mem. 26.

In the Rule, HHS reports that "[a]fter receiving public comments," 84 Fed. Reg. at 7718, it increased its central estimate of capital costs from \$20,000 to \$30,000 per facility, *id.* at 7782. Yet even that trivially increased estimate is still more than 10 to 20 times below the estimates submitted by grantees themselves. HHS still does not identify any data source, assumptions, methodology, or literature that supports its estimates. And HHS still has not estimated any of the ongoing costs of the Separation Requirement, which grantees report will cost them millions more on top of the capital expenses. HHS instead insists, without any evidence, that grantees' estimates were simply too "high," and HHS vaguely anticipates, again without any evidence, that

lower cost methods of compliance will materialize. *Id.* at 7781. Ultimately, HHS seeks to fault the commenters for “not provid[ing] sufficient data to estimate these effects.” *Id.* But it is the responsibility of the agency, not of commenters, to consider the “important aspect[s] of the problem” and “examine relevant data.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Specifically, under its own guidelines for analysis, it was HHS’s responsibility to “use market data . . . obtained through interviews, literature reviews, review of online merchandise catalogues, or other sources” to accurately assess costs. HHS, *Guidelines* at 32. Here, HHS has instead ignored the best evidence before it (*i.e.*, public comments) and offered no other evidence or reasonable theories of how affected clinics could install new waiting rooms, exam rooms, entrances, websites, and personnel, all for just \$30,000.

The Rule’s analysis of direct compliance costs underestimates capital expenses by an order of magnitude and completely ignores tens or hundreds of millions more in ongoing costs. These serious omissions show that HHS arbitrarily failed to examine relevant data, consider important aspects of the problem, and to otherwise engage in the kind of rational analysis required by the Administrative Procedure Act.

III. The Rule’s Enumerated Benefits Are Conclusory and Unsupported by Evidence

HHS lists a number of expected “benefits” of the Rule, including an alleged increase in the number of providers seeking to participate in Title X following the erosion of the nondirective mandate, enhanced patient service and care, and increased compliance with Title X’s prohibition on the use of funds for abortion services. *See* 84 Fed. Reg. at 7777. For each of these expected benefits, the agency makes no attempt to provide evidence supporting its likelihood, nor to estimate the magnitude of these alleged effects. This omission is contrary to both best practices and settled caselaw. Circular A-4 counsels agencies to quantify all benefits

“to the extent feasible.” *Circular A-4* at 45. For those benefits that the agency is unable to quantify, the agency must provide information on why it was unable to quantify the effects of the regulation. *Id.* at 27. HHS guidance on cost-benefit analysis further explains that quantification of a rule’s effects helps to guard against bias and the tendency of “decision-makers . . . [to] weigh nonquantified effects in a manner consistent with their own . . . beliefs.” HHS, *Guidelines* at 47. Therefore, “[c]lear presentation of the available evidence” is needed to support unbiased and transparent reasoning. *Id.*

While HHS claims that the Rule will result in “increased compliance” with rules guarding against the misuse of Title X funds, the agency presents *no* evidence of the misapplication of funds under the present regulatory scheme. 84 Fed. Reg. at 7764. As noted in *Circular A-4*, a regulation’s impact can only be measured against an established baseline. *See Circular A-4* at 15. Without this baseline—i.e., without *any* analysis or evidence of current misuse of funds—the agency cannot convincingly assert that the Rule will “enhance” compliance. *See* 84 Fed. Reg. at 7777. In making claims about enhanced compliance without assessing baseline compliance, HHS arbitrarily ignores an “important aspect of the problem.” *State Farm*, 463 U.S. at 43.

Similarly, HHS provides no evidence for its assertion that the Rule will result in “an expanded number” of providers entering the Title X program. *See* 84 Fed. Reg. at 7777. While HHS acknowledges that it expects some Title X grantees to exit the program in response to the Rule, the agency argues that they will be replaced by new grantees entering the program now that they are permitted to offer only a limited range of contraception services. *See id.* at 7741. However, the agency provides no evidence to support its claim that a larger number of providers will enter the program as exit. *See id.* at 7782. Moreover, these hypothetical new grantees are

unlikely to serve as perfect substitutes for those providers that currently provide a full range of services but must exit the program as their ethical and professional response to the Rule. As a result, some number of patients will lose access to contraceptive services they have come to rely on. HHS nevertheless argues that enabling Title X funding to support clinics that provide only natural planning methods will, in fact, “*decrease* unintended pregnancies... because clients are more likely to visit clinics that respect their views and beliefs.” *Id.* at 7743 (emphasis added). The agency provides no evidence or analysis to estimate how many women, if any, currently do not seek Title X care because of their personal beliefs, nor does the agency provide any rational argument that this body of women outweighs the sizable number that will lose access to the services they current receive under the Title X program.

In assessing whether a regulation is supported by the reasoned explanation required under the APA, courts “do not defer to the agency’s conclusory or unsupported suppositions,” *United Techs. Corp. v. Dep’t of Def.*, 601 F.3d 557, 562 (D.C. Cir. 2010) (quoting *McDonnell Douglas Corp.*, 375 F.3d at 1187). Here, each of the benefits identified by HHS lack evidentiary support and are contrary to both the record and common sense. That the Rule’s entire beneficial impact is comprised of “unsupported suppositions” renders the Rule arbitrary and capricious. *Id.*; *see also State Farm*, 463 U.S. at 43 (An agency may not “offe[r] an explanation for its decision that runs counter to the evidence before [it]”).

CONCLUSION

This Court should grant Plaintiffs’ motions for preliminary injunction.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April, 11 2019, I electronically filed the within Memorandum in Support of Motion for Preliminary Injunction with the Clerk of Court using the CM/ECF system, which will send notification of such filing to counsel of record.

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