UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND
(Northern Division)

PLANNED PARENTHOOD OF MARYLAND, INC., *et al.*, *Plaintiffs*, v. ALEX M. AZAR II, Secretary of the United States Department of Health and Human Services, in his official capacity, *et al.*, *Defendants*.	Civil Action No. CCB-20-00361

OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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SUMMARY OF ARGUMENT

The response by Defendants (hereinafter, "HHS") in this case is most notable for what it does not do. Despite filing a 42-page brief about a rule that elicited more than 74,000 public comments,[1] HHS does not rely on a *single* comment that supports its interpretation of Section 1303 and the Separate-Billing Rule's asserted benefit. Defs.' Opp'n to Pls.' Mot. Summ. J. and Mem. Supp. Defs.' Cross-Mot. Summ. J. 24–29 (hereinafter, "Defs.' Br."), ECF No. 35-1. It does not refute the overwhelming evidence that the Final Rule will drive up costs and reduce insurance coverage, all without making one iota of difference in ensuring that federal funds are not used to pay for non-Hyde abortion services. HHS also does not directly respond to numerous errors identified by Plaintiffs in the Final Rule's analysis, instead contending that the purported "benefit" of aligning the rule with alleged Congressional intent—based on the agency's say-so—can justify the imposition of unlimited costs on the public. And HHS never sets forth a coherent argument regarding whether it believes that Section 1303's plain language requires the Separate-Billing Rule's provisions (in which case HHS is wrong and its calls for *Chevron* deference misguided), or whether it believes that the rule is wholly within its discretion (in which case it cannot point the finger at Congress for the rule's extreme costs or rest on its unfounded assertion that the rule adheres to Congressional intent).

This Court should grant summary judgment to Plaintiffs and deny HHS's cross-motion for summary judgment. The Final Rule's imposition of more than $1.26 billion in costs on the public

[1] *See* Patient Protection and Affordable Care Act; Exchange Program Integrity, Final Rule, 84 Fed. Reg. 71,674 (Dec. 27, 2019) (to be codified at 45 C.F.R. pts. 155, 156); Patient Protection and Affordable Care Act; Exchange Program Integrity, Notice of Correction, 85 Fed. Reg. 2,888 (Jan. 17, 2020); Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program, Interim Final Rule, 85 Fed. Reg. 27,550 (May 8, 2020) (collectively, "the Final Rule" or "the Separate-Billing Rule").

cannot be rational in light of the rule's nonexistent benefits. HHS's cross-motion for summary judgment and opposition simplify the analysis required of this Court because the agency now disavows relying on *any* benefit from the rule other than the rule's purported "better alignment" with Congressional intent. HHS's talismanic invocation of this "benefit" does not hold up to scrutiny. It is unsupported by any serious analysis of indicia that might reveal such intent, such as statutory structure and purpose. Instead, HHS points to a single statement by a single Senator in the legislative debate over Section 1303, a statement not cited in the Final Rule itself. HHS's attorneys' post hoc justification cannot rehabilitate the Final Rule's deficient analysis, even if one stray remark were a reliable indicator of Congressional intent (it is not).

The Final Rule is also arbitrary and capricious based on errors in the agency's cost analysis, which HHS makes no effort to dispute. HHS instead claims that these errors are irrelevant because whatever costs are imposed are required by Section 1303. That argument is doubly wrong. First, the costs of the Separate-Billing Rule—which arise from the rule's requirement that issuers both send separate bills and direct consumers to pay with separate transactions—are not *required* by Section 1303. Second, alleged better alignment with Congressional intent cannot excuse errors in a rule.

The Separate-Billing Rule is also at odds with other portions of Sections 1303 and 1554 in the Patient Protection and Affordable Care Act ("ACA") and is therefore contrary to law under the Administrative Procedure Act ("APA"). HHS's contrary contention would require this Court to read limitations into Section 1554 that are not there and to ignore limitations in Section 1303(b)(3) on HHS's authority.

HHS's objections to Plaintiffs' notice-and-comment claim are equally unavailing. The rule need not directly regulate Plaintiffs for them to suffer an injury-in-fact sufficient to satisfy Article

III standing requirements, and they are in fact injured by the rule, including its Opt-Out Policy. Moreover, binding Fourth Circuit precedent makes clear that the Opt-Out Policy is judicially reviewable as a blanket policy of non-enforcement, *Casa de Maryland v. U.S. Dep't of Homeland Sec.*, 924 F.3d 684 (4th Cir. 2019), *pet. for cert. filed* (U.S. May 24, 2019) (No. 18-1469); it is not akin to the individualized enforcement decisions at issue in *Heckler v. Chaney*, 470 U.S. 821 (1985). And the Opt-Out Policy cannot plausibly be construed as a "general statement[] of policy" that is exempt from notice-and-comment rulemaking under 5 U.S.C. § 553(b)(3)(A). The policy has a binding effect, as evidenced by its mandatory language prohibiting officials from taking enforcement actions and its encouragement to regulated parties to rely on it as a safe harbor.

Finally, if the Court grants summary judgment to Plaintiffs, it should immediately vacate the Separate-Billing Rule and enter an order declaring the rule's invalidity and preventing its enforcement nationwide. This remedy is the presumptive relief afforded under the APA and is the only relief sufficient to fully address Plaintiffs' injuries. In the alternative, the Court should award this relief after first certifying the Proposed Consumer Class under Federal Rule of Civil Procedure 23(b)(2). *See* Consumer Pls.' Mot. for Class Certification, ECF No. 40.

ARGUMENT

I. THE RULE IS ARBITRARY AND CAPRICIOUS

As Plaintiffs have explained, the Separate-Billing Rule is an arbitrary and capricious exercise of agency discretion and therefore invalid under the APA. 5 U.S.C. § 706(2)(A). None of HHS's arguments in response has merit. HHS set forth illogical rationales to support the Final Rule's purported "benefits," and the rule's imposition of more than $1.26 billion in costs on the public, without any discernible, countervailing benefit, is therefore irrational. This conclusion applies with even greater force with respect to the Final Rule's implementation deadline, now extended to August 2020, which compounds costs while increasing consumer confusion by

requiring issuers to comply with the rule in the middle of the plan year in the midst of a pandemic. Moreover, HHS ignored critical costs imposed by the rule, including costs to consumers of paying monthly bills through two transactions instead of one. The agency inexplicably treated these costs as if consumers may not incur them, departing from the proposed rule's analysis.

A. The Rule Is Not Justified by Its Purported Benefits

In its cross-motion for summary judgment, HHS walks away from one of the only two purported "benefits" identified in the Final Rule, asserting that the rule was not adopted to provide "transparency" to consumers who do not wish to purchase or maintain an insurance plan covering abortion. *See* Defs.' Br. 28–29. Just as HHS could not justify the Final Rule based on the two purported "benefits" it identified there, it cannot justify the Final Rule on the single asserted "benefit" that remains at issue: supposed "better alignment" of the regulations with Congressional intent.

1. HHS suggests that Plaintiffs agree with its "conclusion that 'separate payment[s]' require separate transactions and that requiring separate bills better aligns the regulations with Congress's intent to require separate transactions." *Id.* at 24; *see also id.* at 29 (claiming that Plaintiffs do not dispute that the "separate payment" requirement is "best read as a 'separate transaction' requirement"). HHS mischaracterizes Plaintiffs' position.

As Plaintiffs have explained and further address below, even if the term "separate payment[s]" may be capable of more than one reasonable interpretation, it *cannot* require the regime mandated by the Final Rule because doing so would run afoul of Section 1554 of the ACA and conflict with other language in Section 1303 regarding notice to enrollees. *See infra* Parts (II)(A), (C); *see also* Pls.' Br. 32–37. An agency's interpretation of a statute that is contrary to law necessarily cannot be reasonable, much less the "best" interpretation of otherwise ambiguous language. For this reason, HHS's interpretation of Section 1303 also deserves no deference under

Chevron U.S.A., Inc. v. NRDC, 467 U.S. 837 (1984), since such deference is reserved only for an agency's *reasonable* interpretation of an ambiguous statutory provision.[2]

Even if Section 1303's reference to "separate payments" were theoretically capable of the interpretation HHS accords it, the agency still had an obligation to consider that interpretation among others and provide "good reasons" for adopting it. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2124 (2016). It did not do so in the Final Rule, instead supplying a "conclusory" and "unsupported supposition" to which this Court owes no deference. *United Techs. Corp. v. U.S. Dep't of Def.*, 601 F.3d 557, 562 (D.C. Cir. 2010).

As to Section 1303's specific language, HHS does not point to anything in the rule explaining why Congress's use of the term "separate payment[s]" reveals its intent to require "separate transactions," and HHS appears to acknowledge that the two terms are distinct. *See* Defs.' Br. 25 (stating that the Final Rule concluded that the "best reading of Section 1303 was that it requires separate payments *in separate transactions*, and it implemented that Congressional directive" (emphasis added)). Nor does HHS dispute that interpreting the term "payment[s]" to require separate "transactions" is at odds with "ordinary commercial practice," which bears on the proper interpretation of an ambiguous statutory term. *Rai v. WB Imico Lexington Fee, LLC*, 802

[2] *Chevron* deference is particularly inappropriate here, where the agency repeatedly asserts that it did not exercise discretion and in fact "had no authority" to interpret Section 1303's "separate payment" requirement any other way than it did in the Final Rule, that is, by requiring separate transactions from consumers. Defs.' Br. 28; *see also id.* at 27 (stating that HHS was "obliged to determine *how* to require collection of separate payments in distinct transactions, rather than whether to do so at all"); *id.* at 28 (responding to Plaintiffs' assertion that the Final Rule is inconsistent with the ACA's purpose by contending that HHS is "bound not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate"). HHS cannot have it both ways—asking the Court to defer to its judgment in interpreting the law while simultaneously pointing the finger at Congress for the rule's massive costs and nonexistent benefits. *See Shipbuilders Council of Am. v. U.S. Coast Guard*, 578 F.3d 234, 243 (4th Cir. 2009) (recognizing that a regulation is not entitled to deference if it merely parrots a statutory mandate).

F.3d 353, 359 (2d Cir. 2015); *see, e.g.*, Center on Budget and Policy Priorities Comment at 2, AR 081218 (explaining that "[a]dministratively separating funds received through one payment transaction is commonplace" in the insurance industry and that "for example, insurance companies often offer 'bundled' coverage (such as life and health insurance) that combines two distinct types of coverage under one payment transaction").

HHS also points to nothing in the Final Rule demonstrating that its interpretation serves Section 1303's purpose of ensuring that federal funds do not pay for non-Hyde abortion services, or that it advances the ACA's overall purpose of encouraging health insurance coverage and reducing health care costs. Instead, it dismisses comments demonstrating that the rule would result in high out-of-pocket costs; delays in access to care, including abortion care (with attendant enhanced risk to patient health); interruptions in medical treatment for patients with chronic or serious health conditions; and potentially insurmountable financial barriers that impede individuals from obtaining the care they need. *See, e.g.*, Planned Parenthood Federation of America ("PPFA") Comment at 10, AR 079783; American College of Obstetricians & Gynecologists Comment at 5, AR 081311; Physicians for Reproductive Health Comment at 4, AR 070906; American Public Health Association Comment at 4, AR 081296; *see also, e.g.*, Healthcare Association of New York State Comment at 2, AR 078620 (explaining that "loss of coverage for consumers will negatively impact payment to providers for those services" and providers' "ability to provide patient care"). HHS instead claims that these considerations are wholly irrelevant in light of the "specific statutory mandate in Section 1303." Defs.' Br. 24.

HHS's conception of that statutory mandate—that is, its basis for concluding that a $1.26 billion rule is more consistent with Congressional intent than prior rules—appears to rest on a single statement by Senator Nelson during the legislative debate over Section 1303. *See id.* at 10.

In that statement, which HHS did not cite in the Final Rule, Senator Nelson contends that the proposed legislation would require insurance companies to "bill [consumers] separately" for abortion-related premiums and that consumers would have to make "separate payments." Cong. Rec. S14,134 (Dec. 24, 2009) (statement of Sen. Nelson). This statement cannot bear the weight HHS places on it. "[T]he views of a single legislator, even a bill's sponsor, are not controlling" as to a statute's meaning. *Mims v. Arrow Fin. Servs., LLC*, 565 U.S. 368, 385 (2012); *Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 783 n.12 (2000) (refusing to rely on a "single sentence of legislative history" for interpretation of a disputed term's meaning); *accord Nalley v. Mayor & City Council of Balt.*, 796 F. Supp. 194, 198 (D. Md. 1992). A "solitary phrase of a single legislator's comments (which, of course, the members of the other House in our bicameral system would not have had occasion to hear)," hardly establishes Congressional intent. *United States v. McGoff*, 831 F.2d 1071, 1090 (D.C. Cir. 1987). And it cannot justify an agency's interpretation of an ambiguous statutory provision where the agency neither acknowledged nor relied on it for that interpretation. *See, e.g.*, *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d 462, 467–68 (4th Cir. 2013) (holding that a reviewing court "may look only to [an agency's] *contemporaneous* justifications" for its action).

2. HHS also mischaracterizes Plaintiffs' position as to how and when an agency may consider whether a rule aligns with Congressional intent. Plaintiffs are not arguing that the Final Rule's interpretation of Section 1303 had to rely "s*olely* on policy concerns rather than fidelity to Congressional intent." Defs.' Br. 25 (emphasis added). Plaintiffs' point is that when an agency attempts to justify a rule on the view that it is most consistent with Congressional intent, it must consider and supply good reasons—policy-related or otherwise—for that conclusion.

The agency's say-so does not, as HHS would have it, trump all other policy considerations and justify a drastic increase in costs. *See id.* at 26–27. Although HHS cites *Encino Motorcars*, 136 S. Ct. 2117, and *Rust v. Sullivan*, 500 U.S. 173, 187 (1991), in support of its position, it cherry-picks stray phrases from those decisions and uses them entirely out of context. Contrary to HHS's representations, those cases in fact underscore that an agency must supply good reasons for concluding that an interpretation is most consistent with Congressional intent, which HHS did not do here.

Encino Motorcars involved a Department of Labor ("DOL") rule interpreting an exemption to the Fair Labor Standards Act not to apply to "service advisors" who work at car dealerships. 136 S. Ct. at 2123–24. The regulation marked a dramatic departure from the agency's previous interpretation of the statute, on which regulated parties had depended for decades. The Supreme Court held that the agency failed to provide a reasoned explanation for its new interpretation, which the agency asserted was more consistent with the statute. Although the Court acknowledged that "an agency may justify its policy choice by explaining why that policy is more consistent with statutory language than alternative policies," *id.* at 2127 (internal quotation marks omitted)), it concluded that DOL "said almost nothing" to support that conclusion, *id.* (quoting *FCC v. Fox Television Stations*, 556 U.S. 502, 515 (2009)). *See also id.* (faulting the agency for "not analyz[ing] or explain[ing] why the statute should be interpreted" as the agency urged); *id.* (noting that although "several public comments supported the Department's reading of the statute, the Department did not explain what (if anything) it found persuasive in those comments beyond the few statements above").

The Final Rule suffers from precisely the same problem. In the rule, HHS claimed that its interpretation is better aligned with Congressional intent but failed to supply any foundation for

that conclusion. HHS did not rely there—and does not rely in its brief—on a single public comment supporting its interpretation of Section 1303. *See also* 84 Fed. Reg. at 71,684 (acknowledging that only a "minority" of commenters supported the rule and did so "summarily"). HHS now points only to Senator Nelson's to support its position, but it did not even cite that statement in the Final Rule and the statement is, in any event, insufficient to support the rule. Accordingly, the Final Rule suffers from the same flaws as the rule in *Encino Motorcars* and should likewise be held invalid.

HHS's reliance on *Rust* is also unavailing. That case involved an APA challenge to regulations that interpreted the federal Title X family planning program "to require a ban on counseling, referral, and advocacy [on abortion] within the Title X project." *Rust*, 500 U.S. at 184. The Supreme Court upheld the rules, despite their departure from the agency's prior interpretation of Title X, by emphasizing that, to engage in informed rulemaking, an agency "must consider varying interpretations and the wisdom of its policy on a continuing basis" and must remain able to "adapt its rules and policies to the demands of changing circumstances." *Id.* at 186–87 (internal quotation marks and alteration omitted). The Court did *not* conclude, as HHS suggests, that the regulations were permissible simply because the agency believed them to be "more in keeping with the original intent of the statute." *Id.* at 187. Rather, the Court explained, for example, that the agency had also relied on government investigations and reports showing "that prior policy failed to implement [the statute] properly" and that grantees needed more guidance. *Id.* The agency also supported its new interpretation based on its views regarding "client experience under the prior policy." *Id.*

Here, HHS "offers no data, studies or other references to indicate that the current structure is failing to shield public funds from paying for abortion services," Connecticut Office of the Healthcare Advocate Comment at 3–4, AR 080991–92, or that the flexible approach previously in

place was unworkable. Moreover, unlike in *Rust*, HHS expressly disavowed reliance on a dated Government Accountability Office report regarding Section 1303's implementation and issuer compliance. 84 Fed. Reg. at 71,692.

In sum, HHS's contention that the Final Rule is justified by the sole "benefit" of better alignment with the statute is entirely unsupported.

B. The Separate-Billing Rule's Imposition of Massive Costs for No Discernible Benefit Is Irrational

As Plaintiffs have explained, the Final Rule is an overwhelmingly expensive "solution for a non-existent problem." DC Health Benefit Exchange Authority Comment at 2, AR 080936. Its imposition of massive costs for no discernible benefit is arbitrary and capricious under the APA. *See Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015). HHS's attempt to avoid review of this decision is unconvincing.

1. In its opposition, HHS does not dispute that the rule will cost more than $1.26 billion to implement and have draconian effects on enrollees, including those who inadvertently do not comply with the requirement to make separate premium transactions. *See, e.g.*, PPFA Comment at 6, AR 079779 (citing a study showing that sixty percent of consumers who were given two separate bills requiring separate fund transfers to purchase health insurance "did not complete the process correctly"); Blue Shield of California Comment at 2, AR 081321 (describing 100,000 current enrollees who re-enroll in coverage each year by making automatic credit card payments, each of whom would risk losing coverage if they failed to establish a second automatic transaction to re-enroll). HHS also does not contest that the Final Rule is exponentially more expensive—up to *4,000 times* more in at least one respect—than HHS had initially anticipated, yet the Final Rule largely carries over the Proposed Rule's terms. *See generally* Defs.' Br. at 29–33. And HHS offers no justification for the Final Rule's unexplained departure from the Proposed Rule, which treated

as certain and quantifiable those costs arising from consumers' need to make separate payment transactions. *See* Pls.' Br. 16, 28.

Instead, HHS blames Congress for all these costs. It now acknowledges that consumers are certain to incur costs related to making payments through two separate transactions each month and paying premium increases caused by the rule, but it claims these costs are a "consequence of the separate transaction requirement in [Section 1303], no matter how it may be implemented." Defs.' Br. 33; *see also, e.g., id.* at 29 (claiming that "requiring issuers to collect separate payments in separate transactions" was a "choice . . . made in Congress"). HHS thus makes the remarkable assertion that it had "no obligation to respond" to these comments in the first place because, no matter the costs, they would not have "required a change" in the Proposed Rule. *Id.* at 30.

This argument is flatly contrary to the Supreme Court's rationale in *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015). *See* Pls' Br. 26. HHS asserts that *Michigan* at most requires agencies to pay only "some attention to cost," Defs.' Br. 31, and that the agency did so here. But nothing in *Michigan* stands for the proposition that an agency's cost analysis could be littered with errors and inconsistencies and nevertheless satisfy the APA's demand for reasoned decisionmaking. So, for example, in *Nicopure Labs, LLC v. Food & Drug Administration*, 266 F. Supp. 3d 360 (D.D.C. 2017), *aff'd on other grounds*, 944 F.3d 267 (D.C. Cir. 2019), on which HHS relies, the Court first considered whether an agency had paid sufficient attention to costs under *Michigan* and then proceeded to consider whether the agency's analysis of those costs was reasonable. *See id.* at 403–07.

HHS's argument that Congress required the costs related to separate payment transactions also makes no sense. As described above, Section 1303 says absolutely nothing about whether "separate payments" must be collected from enrollees through "separate transactions." HHS's own

analysis in the Final Rule confirms as much. Although it made no attempt to quantify costs to consumers related to making separate transactions each month, nor even acknowledge that those costs were certain to be incurred, it *did* attempt to quantify costs to issuers related to their acceptance and reconciliation of those separate transactions. *See* 84 Fed. Reg. at 71,698. Were HHS correct about Section 1303's mandate, the agency would have had no obligation to consider those costs, either.

Moreover, HHS's assertion that premium increases will be driven by costs required under Section 1303's "'separate transaction' requirement," Defs.' Br. 29, and are therefore not imposed by the rule itself, is plainly wrong. The Separate-Billing Rule is clear that the costs to issuers of separate *billing* will be the primary driver of the rule's burdens on issuers, which in turn will affect how issuers set premium levels. *Compare* 84 Fed. Reg. at 71,704 (estimating that activities under the separate-transaction requirement, such as "processing and reconciling separate payments," would cost issuers $94 million annually), *with id.* at 71,698–99 (estimating that activities under the separate-billing requirement, such as "ensuring billing accuracy" and "print[ing] separate bills for impacted policy holders," would cost issuers over $100 million annually; *see also id.* at 71,697 (estimating that implementation of technical changes and "billing-related outreach" under the Final Rule would incur a one-time cost of $385 million to issuers). HHS has never argued that these *billing*-related costs flow directly from the statute, so premium increases driven by them cannot flow from the statute, either.

2. HHS spills much ink arguing that the APA does not require it to quantify costs and benefits, and that not all costs and benefits are capable of quantification. *See* Defs.' Br. 30–32. Plaintiffs do not claim otherwise. Their point is, and has been, that the rule's costs and benefits are an "important aspect of the problem," *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*,

463 U.S. 29, 43 (1983), and thus bear on its rationality. *See also N.C. Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 769 (4th Cir. 2012) ("[T]he agency is obligated to identify and respond to relevant, significant issues raised during those proceedings."). Accordingly, where the agency assesses costs and benefits, in quantified or unquantified terms, it cannot do so irrationally.

Under this standard, the Final Rule is arbitrary and capricious. It is not rational to "impose billions of dollars in economic costs in return for a few dollars in [other] benefits," *Michigan,* 135 S. Ct. at 2707, much less in return for some vague notion that the agency's current interpretation is simply "better" than its previous, more flexible one. *See also Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 225–26 (2009) ("[W]hether it is 'reasonable' to bear a particular cost may well depend on the resulting benefits . . . ."). Nor is it rational to treat costs to issuers of accepting payments through separate transactions as both certain and quantifiable, while disregarding the analogous costs to *consumers* and suggesting that consumers may not even incur them. *See* 84 Fed. Reg. at 71,701 (identifying only in qualitative terms "[p]otential increased costs incurred by enrollees who *choose* to make separate payments for coverage of non-Hyde abortion services" (emphasis added)); *id.* at 71,706 (stating that "the burden may be moderately higher for those policy holders who follow instructions to pay in separate transactions" than for those who do not). This "unexplained inconsistency" in HHS's rationale supports finding that the rule is arbitrary and capricious. *Jimenez-Cedillo v. Sessions*, 885 F.3d 292, 298 (4th Cir. 2018).

C. HHS Adopted an Arbitrary Implementation Deadline

The Final Rule's implementation date—originally set for June and now extended to August 26, 2020—is likewise arbitrary and capricious.[3] As Plaintiffs have explained, the Blue Cross Blue

[3] On May 8, 2020, after the parties filed their cross-motions for summary judgment, HHS published an Interim Final Rule ("IFR") that postponed the Separate-Billing Rule's

Shield Association ("BCBSA"), which represents issuers across the country, told HHS that most "would need up to two years for implementation." BCBSA Comment at 4, AR 080264. America's Health Insurance Plans ("AHIP") likewise stated that more than two-thirds surveyed would need at least eighteen months to comply. AHIP Comment at 11, AR 080215. Alongside the National Association of Insurance Commissioners ("NAIC"), they warned that forcing the implementation of the rule in the middle of the 2020 plan year would increase consumer confusion and leave issuers without a sufficient amount of time to test new systems required to comply with the rule and to train customer service staff. *See, e.g.*, AHIP Comment at 11, AR 080215; BCBSA Comment at 5, AR 080265; NAIC Comment at 1–2, AR 079065–66; *see also* Connect for Health Colorado Comment at 8, AR 081101 (describing need for extended period of time to develop "consumer education materials aimed at reducing the muddle created" by the rule).

HHS did not seriously respond to these comments in the Final Rule or explain why it did not believe them to be reliable, instead asserting without support that a six-month implementation deadline was reasonable to "appropriately prioritize[] the goals of improved statutory alignment," 84 Fed. Reg. at 71,689, and was necessary to ensure "transparency" as to whether plans cover non-Hyde abortion services, *id.* at 71,690. HHS now attempts to rehabilitate the Final Rule by offering post hoc justifications for its arbitrary implementation deadline, but none of those justifications is convincing.

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implementation deadline by sixty days, to August 26, 2020, in light of the COVID-19 pandemic. *See* 85 Fed. Reg. at 27,553. Plaintiffs have moved to supplement their complaint to challenge the IFR. *See* Pls.' Mot. Leave File Am. and Suppl. Compl. for Declaratory and Injunctive Relief as to Named Pls. and Proposed Class, ECF No. 39. Should that motion be granted, Plaintiffs respectfully request the opportunity to address in short letter briefs why the August 2020 implementation date remains arbitrary and capricious.

First, HHS faults the issuer representatives for not describing the basis for their time estimates in comments. That criticism is misplaced. The issuers exhaustively detailed the many steps required to implement the rule, and the staffing needs involved in them. *See, e.g.*, AHIP Comment at 17–19, AR 080221–23; BCBSA Comment at 4–5, AR 080264–65. In any event, HHS provides no reason for its rejection of this "specific, contradictory evidence" from regulated entities that are actually familiar with the tasks involved, *Ergon-W. Va., Inc. v. EPA*, 896 F.3d 600, 613 (4th Cir. 2018), while accepting a six-month implementation date that *no* issuer or its representative—or any other commenter with expertise, including the National Association of Insurance Commissioners—indicated would be reasonable. *See United States v. F/V Alice Amanda*, 987 F.2d 1078, 1085 (4th Cir. 1993) (recognizing that a court "need not 'accept without question administrative pronouncements clearly at variance with established facts'" (quoting *Nat'l Labor Relations Bd. v. Morganton Full Fashioned Hosiery Co.*, 241 F.2d 913, 915–16 (4th Cir. 1957))); *Gresham v. Azar*, 950 F.3d 93, 103 (D.C. Cir. 2020) ("Nodding to concerns raised by commenters only to dismiss them in a conclusory manner is not a hallmark of reasoned decisionmaking.").

HHS also contends that commenters do not say it would be *impossible* for some issuers to comply within six months, "even with increased expenditure," and it suggests that the majority of issuers who need eighteen months or more for implementation could rely on HHS's statement's regarding its exercise of enforcement discretion for a one-year delay in implementation. Defs.' Br. 35–36. That argument ignores the record, in which issuers and their representatives identified the time period "necessary" to comply, not just necessary to avoid increased costs. AHIP Comment at 11, AR 080215; BCBSA Comment at 4, AR 080264; *see also* NAIC Comment at 1–2, AR 079065 (urging that any changes be implemented at the beginning of a plan year, when "[c]onsumers can

more easily adapt to new payment arrangements"). HHS's argument is also at odds with the Final Rule, which indicated that the agency expects to exercise its enforcement authority to delay implementation only for those issuers "fac[ing] uncommon or unexpected impediments to timely compliance." 84 Fed. Reg. at 71,689. The Final Rule is therefore clear that delayed implementation will not be available to the majority of issuers (and is therefore not equivalent, as HHS suggests (Defs.' Br. 36), to seriously considering an implementation deadline beyond six months). Yet the record indicates that the majority of issuers will need a delay of that length, if not more.

Moreover, even if some issuers can comply within six months, the expenditure required to do so (estimated by HHS to be a fifty percent premium, *see id.*) is not reasonable. HHS asserts that rapid implementation of the rule will yield the "benefit" of aligning it with Section 1303. However, the purported "benefit" of statutory alignment does not justify this cost (or "any other particular amount" of administrative costs, as HHS remarkably suggests), *id.*, for the same reasons this purported benefit cannot support the rest of the rule. *See supra* Part I(A).

D. HHS Failed to Consider the Impact of the Opt-Out Policy on Issuers and Enrollees Who Seek to Maintain Abortion Coverage

As Plaintiffs have explained, in addition to adopting the Opt-Out Policy despite a conflict with Section 1303's plain language and without notice-and-comment rulemaking, *see infra* Parts II and III, HHS did not consider the financial impact of this policy on plans and enrollees who seek to maintain abortion coverage. Its failure to consider this "important aspect of the problem," *State Farm*, 463 U.S. at 43, renders the Final Rule arbitrary and capricious.

In response, HHS faults Plaintiffs for not specifying "what they anticipate th[e] impact [of the Opt-Out Policy] would be or why it should affect HHS's exercise of enforcement discretion." Defs.' Br. 36. HHS's criticism is misplaced. Plaintiffs have demonstrated that, as the number of opt-outs grows, an issuer permitting such opt-outs will have to either forgo abortion-related

premium payments from enrollees opting out or recalculate the abortion-related premium payment by dividing total costs only by the number of enrollees who retain abortion coverage. *See* 42 U.S.C. § 18023(b)(2)(B); Pls.' Br. 31–32. Accordingly, the Opt-Out Policy will directly increase issuer or consumer costs, or both, a consideration relevant to whether HHS should have adopted a policy of non-enforcement, as it did here.[4]

HHS's only substantive response is to claim that its modifications to the Proposed Rule, including but not limited to the Opt-Out Policy, will reduce costs to issuers of continuing to offer abortion care as compared to the Proposed Rule. Defs.' Br. 37. But that argument is quite beside the point, focusing not on the Opt-Out Policy specifically and drawing a contrast only with the (equally unreasonable) Proposed Rule.

II. THE SEPARATE-BILLING RULE IS INCONSISTENT WITH THE ACA

A. Section 1554 Forbids the Separate-Billing Rule

Section 1554 of the ACA bars HHS from adopting regulations that "create[] any unreasonable barriers to the ability of individuals to obtain appropriate medical care," "impede[] timely access to health care services," or "limit[] the availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. § 18114. As Plaintiffs have explained, *see* Pls.' Br. 32–34, the Separate-Billing Rule is precisely the kind of regulation that Section 1554 forbids and is, therefore, "contrary to law" and invalid under the APA. 5 U.S.C. § 706(2)(B).

HHS contends that Section 1554 applies only to some undefined subset of regulations adopted pursuant to the ACA that "speak directly to the provision of health care" or

[4] To the extent that HHS contends Plaintiffs should have been even more specific about the policy's expected impact, its argument only underscores why the Opt-Out Policy should have gone through notice-and-comment rulemaking, where such evidence could have been developed in the administrative record, thus helping to "ensure informed agency decisionmaking." *N.C. Growers' Ass'n*, 702 F.3d at 763 (emphasizing that the importance of "notice and comment procedure cannot be overstated").

"communications between provider and patient," and then only bars those regulations that involve "*direct* government interference with health care." Defs.' Br. 20, 22. It argues that the Separate-Billing Rule is not such a regulation because it addresses "the question of how issuers collect and maintain payments from enrollees for coverage." *Id.* at 22.

HHS's limited construction of Section 1554 finds no home in the broad statutory text, which the Court cannot "replace . . . with speculation as to Congress' intent." *Magwood v. Patterson*, 561 U.S. 320, 334 (2010). Rather, the Court "must presume that [the] legislature says in a statute what it means and means in a statute what it says there." *Dodd v. United States*, 545 U.S. 353, 357 (2005) (quoting *Conn. Nat'l Bank v. Germain,* 503 U.S. 249, 253–54 (1992)). If Congress had intended to limit Section 1554's reach in the manner HHS suggests, it would have said so. It did not.

Instead, Congress specifically defined "medical care" to include "amounts paid for insurance covering" such care. 42 U.S.C. § 300gg-91(a)(2). Section 1554's prohibition on "unreasonable barriers to the ability of individuals to obtain appropriate medical care," *id.* § 18114, therefore, covers barriers to insurance payments for such care. More generally, access to health insurance plainly bears on "timely access to health care services" and "the availability of health care treatment for the full duration of a patient's medical needs," *id.*, which explains why Congress included Section 1554 in a statute that "aim[ed] to increase the number of Americans covered by health insurance and decrease the cost of health care." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 538 (2012); *Elec. Welfare Tr. Fund v. United States*, 907 F.3d 165, 166 (4th Cir. 2018) (recognizing the ACA's "reform[s] [to] several features of the health insurance industry"). HHS's attempt to remove the Separate-Billing Rule from Section 1554's scope cannot withstand scrutiny.

HHS also contends that to the extent there is a conflict between Section 1554 and Section 1303, the general-specific canon of statutory construction supports giving effect to Section 1303's requirements because that Section 1303 supplies the more specific rule. Defs.' Br. 21. This argument is beside the point. It is the Separate-Billing Rule, not Section 1303, that conflicts with Section 1554. Without conflict "between . . . two statutory provisions," there is simply "no need for an interpreting court to resort to the general-specific canon to determine Congressional intent." *Lara-Aguilar v. Sessions*, 889 F.3d 134, 141 (4th Cir. 2018), *cert. denied sub nom. Lara-Aguilar v. Whitaker*, 139 S. Ct. 621 (2018). HHS provides no authority for extending the reach of the general-specific canon to instances in which an agency, relying on its discretion to interpret a statutory provision, interprets that provision in a manner inconsistent with another provision of law. Were HHS correct, it could impose extensive barriers to patient care by simply claiming to "interpret" statutory provisions within its discretion. In any event, the plain language of Section 1554 provides that "[n]otwithstanding any other provision of this Act," that is, any other provision of the ACA, "the Secretary of [HHS] shall not promulgate any regulation" that imposes the burdens that Section 1554 forbids. 42 U.S.C. § 18114. Thus, to the extent a conflict exists, Congress was clear in Section 1554 that the broad reach of that provision necessarily trumps all others, including Section 1303.

HHS also argues that ruling for Plaintiffs would permit challenges to "*any* regulation" adopted pursuant to any statute that HHS administers, where the regulation "could even *potentially* raise health care costs or indirectly lead to a reduction in coverage, no matter how speculative the chain of contingencies." Defs.' Br. 20–21. A ruling in Plaintiffs' favor would have no such effect. It takes no speculative leap to conclude—as HHS in fact *did* when it adopted the Separate-Billing Rule—that the rule will cause some patients to lose all their insurance coverage due to inadvertent

non-payment of the abortion-related premium, incurring out-of-pocket costs and experiencing interruptions in their healthcare. 84 Fed. Reg. at 71,688. The agency also acknowledged that the rule will lead to an annual consumer premium increase of up to one percent, and that enrollment in the exchanges "will be reduced" as a result of these increases. *Id.* at 71,704. HHS further recognized that some insurers will drop abortion coverage, and although it did not quantify the out-of-pocket costs to affected enrollees, it acknowledged that some enrollees would incur costs for abortion care that were previously covered by insurance, which could delay access to abortion as enrollees attempt to raise the necessary funds. *Id.* at 71,705, 71,688; *see also, e.g.*, Association of Community Affiliated Plans Comment at 5, AR 081168 (describing issuers dropping non-Hyde abortion coverage as "easily anticipated"). The Separate-Billing Rule—which claims to implement a provision of the ACA adopted by the very same Congress as Section 1554—harms rather than helps patients, and it does so in exactly the ways that Section 1554 forbids. The Court need not look any further than that to rule in Plaintiffs' favor.

HHS's reliance on *California by & through Becerra v. Azar*, 950 F.3d 1067 (9th Cir. 2020) (en banc), *see* Defs.' Br. 20, to avoid Section 1554's application is misplaced. The plaintiffs in *Becerra* argued that Section 1554 barred regulations that purported to implement the federal Title X family planning program, which is not part of the ACA. *Id.* at 1094. The Ninth Circuit held that Section 1554 did not sweep so far. It concluded that Section 1554 was concerned with protecting patients and providers from regulatory burdens under the ACA, not with separate federal grant programs in which Congress necessarily must choose what to fund. *Id.* at 1094–95. Regardless of whether *Becerra* was correct on its own terms, the Separate-Billing Rule, by contrast, claims to interpret Section 1303, which *is* part of the ACA, and it imposes massive regulatory burdens on issuers and consumers alike. In such a situation, *Becerra* is clear that, "in the event of a clash" like

this one, Section 1554 "would supersede" regulations imposing such burdens. *Id.* at 1094 (citations omitted).

B. The Final Rule's Opt-Out Policy Contradicts Section 1303's Mandate Regarding Collection of an Abortion-Related Premium

As Plaintiffs have explained, Section 1303 requires that issuers offering non-Hyde abortion coverage in exchange plans "shall . . . collect from each enrollee" the portion of the premium attributable to non-Hyde abortion care, in addition to the rest of the premium. 42 U.S.C. § 18023(b)(2)(B)(i). Congress's use of the word "shall" in this provision imposes a "discretionless obligation[]" on issuers to collect an abortion-related premium in plans that offer abortion coverage. *Lopez v. Davis*, 531 U.S. 230, 241 (2001). The Final Rule's Opt-Out Policy is contrary to this statutory mandate and therefore invalid.

1. Plaintiffs have standing to challenge the Opt-Out Policy

HHS contends that Plaintiffs lack Article III standing to challenge the Opt-Out Policy, but each of its arguments is meritless. First, HHS argues that the Opt-Out Policy addresses "enforcement actions *against issuers*," not enrollees. Defs.' Br. 12. That distinction is irrelevant: it is well-established that a plaintiff suffering an injury-in-fact fairly traceable to a challenged agency action need not be directly regulated by the action to have standing sufficient to satisfy Article III. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992); *Mendoza v. Perez*, 754 F.3d 1002, 1010 (D.C. Cir. 2014); *see also, e.g.*, *Air Evac EMS, Inc. v. Cheatham*, 910 F.3d 751, 760 (4th Cir. 2018) (holding that Article III does not require a plaintiff to show that a defendant's conduct was "the last link in the causal chain" that led to plaintiff's injury).

Second, HHS contends that the Opt-Out Policy "creates no burdens or costs on Plaintiffs." Defs.' Br. 12. But that claim is at odds with the Opt-Out Policy's operation, which allows policy holders to opt out of abortion coverage while remaining in a plan that includes such coverage. 84

Fed. Reg. at 71,686–87. The policy necessarily reduces the pool of enrollees contributing funds toward abortion-related services and, either directly or through issuers, then forces enrollees who continue to pay the abortion-related premium to shoulder the burden of opt-outs. *See id.* at 71,706 (acknowledging that under the Opt-Out Policy, issuers would have to either accept enrollees' failure to contribute funds towards non-Hyde abortion services or else "experience a higher number of enrollee terminations as a result of delinquent premium payments"); *cf. id.* at 71,704 (estimating that the Final Rule would lead to an increase in consumer premiums of up to one percent annually). Plaintiffs' declarations demonstrate that they would be among any remaining pool of enrollees left to shoulder the abortion-related premium costs.[5]

HHS also contends that Plaintiffs lack standing to challenge the Opt-Out Policy because states can continue to enforce the ACA's substantive mandates against issuers, thus preventing issuers from permitting opt-outs and precluding any harm to Plaintiffs. That rationale is hollow. As Plaintiffs have explained, Pls.' Br. 34–35, the Opt-Out Policy reinterprets Section 1303 to permit an issuer—through opt-outs—to create "a modified plan that does not cover non-Hyde abortion services," and thereby removes an enrollee's otherwise applicable "obligation to pay the required premium for such services." 84 Fed. Reg. at 71,686. HHS does not explain how a state could continue to exercise "enforcement authority to ensure compliance with the requirements of Section 1303," Defs.' Br. 12, when HHS has interpreted Section 1303 in this manner. It also strains credulity for HHS to argue now that issuers will not actually adopt policies to permit consumers

[5] HHS is wrong to suggest (at Defs.' Br. 8 n.1) that there is anything improper about Plaintiffs' submission of declarations to demonstrate the ways in which the Final Rule will injure them. *See, e.g.*, *Sierra Club v. EPA*, 292 F.3d 895, 901 (D.C. Cir. 2002) (directing that where a party's standing is not clear from the administrative record, the party should "fil[e] additional affidavits or other evidence sufficient to support its claims").

to opt out of abortion coverage, either because of state enforcement threats or otherwise; presumably HHS did not adopt the Opt-Out Policy to have no meaningful impact on enrollees and their plans.

In any event, even if Plaintiffs cannot show they are injured by the Opt-Out Policy specifically, they have standing to challenge it because the Opt-Out Policy is not severable from the remainder of the rule. *See, e.g.*, *INS v. Chadha*, 462 U.S. 919, 932 (1983) (considering whether a challenged provision was severable from the remainder of the statute in assessing standing); *Am. Fed'n of Gov't Employees v. United States*, 634 F. Supp. 336, 340 (D.D.C. 1986) (same), *aff'd sub nom. Bowsher v. Am. Fed'n of Gov't Employees, AFL-CIO*, 479 U.S. 801 (1986); *see also, e.g.*, *Lamar Advert. of Penn, LLC v. Town of Orchard Park*, 356 F.3d 365, 375 n.13 (2d Cir. 2004) (citing cases to this effect). Accordingly, invalidation of the Opt-Out Policy would require wholesale invalidation of the rule, a remedy that would redress Plaintiffs' injuries from the separate-billing and separate-transaction requirements. *Lujan*, 504 U.S. at 561; *see also* Pls.' Br. 19 (describing harms to Plaintiffs).

In assessing whether a portion of a regulation is severable, courts look at the "issuing agency's intent," *North Carolina v. FERC*, 730 F.2d 790, 795–96 (D.C. Cir. 1984) (citing *FPC v. Idaho Power Co.*, 344 U.S. 17, 20–21 (1952)), and whether the challenged section is "functional[ly] independen[t]" from the rest of the rule, *W. Va. Ass'n of Cmty. Health Ctrs., Inc. v. Sullivan*, 737 F. Supp. 929, 942 (S.D. W. Va. 1990); *see also, e.g.*, *Mayor & City Council of Balt. v. Azar*, No. RDB-19-1103, 2020 WL 758145, at *16–17 (D. Md. Feb. 14, 2020), *hearing en banc ordered*, 799 F. App'x 193 (4th Cir. 2020), *as amended*, (Mar. 30, 2020), *as amended*, (Mar. 31, 2020). Both factors make clear that the Opt-Out Policy is not severable here. HHS explained that it adopted the policy in part to offset another problem created by the Separate-Billing Rule:

"the risk of terminations related to [enrollees'] inadvertent failure to pay the separately billed amount" for abortion-related coverage. 84 Fed. Reg. at 71,686; *id.* at 71,687 (describing the Opt-Out Policy as necessary to "mitigat[e] the serious negative risks of coverage loss by enrollees"); *id.* (describing the Opt-Out Policy as part of the agency's "balanc[ing]" of Section 1303's requirements alongside protection for "enrollees against inadvertent losses of coverage"). In this way, the Opt-Out Policy is closely "intertwined" with the remainder of the rule and intended to operate in tandem with it. *Davis Cty. Solid Waste Mgmt. v. EPA*, 108 F.3d 1454, 1459 (D.C. Cir. 1997) (quoting *Tel. & Data Sys. v. FCC*, 19 F.3d 42, 50 (D.C. Cir. 1994)). Given the agency's own description of the Opt-Out Policy's function within the broader Separate-Billing Rule, and the fact that it is functionally dependent on other parts of the rule, "there is substantial doubt that the agency would have adopted" the same rule absent the Opt-Out Policy. *Epsilon Elecs., Inc. v. U.S. Dep't of Treasury, Office of Foreign Assets Control*, 857 F.3d 913, 929 (D.C. Cir. 2017). Under these circumstances, the Opt-Out Policy is plainly not severable, *id.*, and Plaintiffs are entitled to challenge it.

2. The Opt-Out Policy is judicially reviewable

Under the APA, "there is a 'strong presumption' in favor of judicial review of agency action." *Speed Mining, Inc. v. Fed. Mine Safety & Health Review Comm'n*, 528 F.3d 310, 316 (4th Cir. 2008) (quoting *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986)). HHS contends, however, that the Opt-Out Policy falls within a "narrow exception" to this presumption, *Heckler*, 470 U.S. at 830 (citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971)), because the policy pertains to the exercise of the agency's enforcement discretion, and is therefore "committed to agency discretion by law," 5 U.S.C. § 701(a)(2). To the contrary, the Opt-Out Policy is judicially reviewable.

HHS's argument relies primarily on *Heckler v. Chaney*, Defs.' Br. 12–15, but nothing in *Heckler* supports insulating the Opt-Out Policy from judicial review. In that case, a group of individuals on death row asked the Food and Drug Administration ("FDA") to take enforcement action to prevent the use of certain drugs in lethal injections because the FDA had not approved the drugs for that purpose. 470 U.S. at 823–24. The Supreme Court held that the FDA's refusal to initiate enforcement in that circumstance was unreviewable, *id.* at 838, and emphasized that individual enforcement decisions typically involve a "complicated balancing" of factors, such as "whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, [and] whether the particular enforcement action . . . best fits the agency's overall policies," *id.* at 831. Importantly, *Heckler* expressly reserved the question whether a "general policy" of non-enforcement would be judicially reviewable under the APA. *Id.* at 833 n.4.

Since *Heckler*, the Fourth Circuit and numerous other courts have held that "an agency's expression of a broad or general enforcement policy based on the agency's legal interpretation is subject to review." *Casa de Maryland*, 924 F.3d at 699 (collecting cases); *see also, e.g.*, *OSG Bulk Ships, Inc. v. United States*, 132 F.3d 808, 812 (D.C. Cir. 1998) (providing that "an agency's adoption of a general enforcement policy is subject to review").

In *Casa de Maryland*, for example, the Fourth Circuit concluded that an agency memorandum rescinding DACA, an immigration policy that deferred removal of certain undocumented individuals from the United States, was judicially reviewable, despite the policy's clear bearing on the agency's immigration enforcement decisions. As the court of appeals explained, the agency "did not exercise [its] discretion in an individual case" when adopting the policy or "identify a violation of [the immigration law] against which to act, determine whether

government resources would be best spent enforcing one violation over another, or decide whether the Department would succeed if it pursued a particular violation." *Casa de Maryland*, 924 F.3d at 698–99. Rather, the rescission memorandum operated as a broad enforcement policy, which is "more likely to be [a] direct interpretation[] of the commands of the substantive statute rather than the sort of mingled assessments of fact, policy, and law that drive an individual enforcement decision." *Id.* at 699 (quoting *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 677 (D.C. Cir. 1994)).

The Opt-Out Policy "fits well within this rubric." *Id.* It operates as a blanket assurance to regulated parties that HHS "will not" take enforcement action against them. 84 Fed. Reg. at 71,686; *see also id.* at 71,687 (describing provision as an "interim enforcement polic[y]"). The Opt-Out Policy does not identify any factors that an HHS official might consider prospectively when deciding whether to take enforcement action, nor does it address any particular application of the policy or how the agency's resources could best be utilized among competing priorities. *See Casa de Maryland*, 924 F.3d at 698–99. Indeed, the policy does not leave any discretion to agency officials to take enforcement action while the policy remains in place.

That HHS may one day change the policy, as HHS suggests, *see* Defs.' Br. 39, is irrelevant and is, in fact, always true with respect to agency action, even rules published in the Code of Federal Regulations. Likewise, although HHS points to a statement in the Opt-Out Policy that an issuer providing opt-outs would be expected "to take appropriate measures to distinguish between a policy holder's inadvertent non-payment [of the abortion-related premium] and a policy holder's intentional non-payment," 84 Fed. Reg. at 71,687, that caveat does not render the policy a "mingled assessments of fact, policy, and law that drive an individual enforcement decision." Defs.' Br. 16

(quoting *Casa de Maryland*, 924 F.3d at 699). Nothing in the rule says that this distinction will actually inform the agency's assurance of non-enforcement.

To the extent that an enforcement policy must also interpret a statutory mandate to be reviewable under the APA, *see Casa de Maryland*, 924 F.3d at 699, the Opt-Out Policy does so. Specifically, it adopts HHS's view that an opt-out effectively creates "a modified plan that does not cover non-Hyde abortion services," and thereby removes an enrollee's otherwise applicable "obligation [under Section 1303] to pay the required premium for such services" when they are part of the enrollee's "plan." 84 Fed. Reg. at 71,686. Thus, the Court can undoubtedly review the Opt-Out Policy.

C. The Separate-Billing Rule Conflicts with the ACA's Notice Rules for Abortion Coverage

As Plaintiffs explained in their Motion for Summary Judgment, the Separate-Billing Rule is at odds with Section 1303(b)(3), a separate subsection of the ACA that sets out detailed "[r]ules relating to notice" of a plan's abortion coverage. Under those rules, an exchange plan providing non-Hyde abortion coverage "shall provide a notice to enrollees, *only* as part of the summary of benefits and coverage explanation, at the time of enrollment, of such coverage." 42 U.S.C. § 18023(b)(3)(A) (emphasis added). That notice, along with "any advertising used by the issuer with respect to the plan, any information provided by the Exchange, and any other information specified by" HHS "shall provide information *only* with respect to the total amount of the combined payments for [non-Hyde abortion services] and other services covered by the plan." *Id.* § 18023(b)(3)(B) (emphasis added). Because the Separate-Billing Rule requires issuers to give enrollees notice of abortion coverage and the specific cost of that coverage every single month, it conflicts with Section 1303(b)(3)'s plain terms.

HHS's contrary reading cannot withstand scrutiny. In HHS's view, it appropriately interpreted "notice" in Section 1303(b)(3)(A) not to include bills or invoices, and while Section 1303(b)(3)(B) recognizes that HHS may designate "other information" that may include only the total cost of coverage, HHS has broad authority to identify such "other information" and has not placed bills or invoices in this category.

As an initial matter, "unless otherwise defined, words [must] be interpreted as taking their ordinary, contemporary, common meaning." *Perez v. Cuccinelli*, 949 F.3d 865, 873 (4th Cir. 2020) (citing *United States v. Mills*, 850 F.3d 693, 697 (4th Cir. 2017)). HHS's interpretation of "notice" at the time of enrollment not to include a bill or invoice is inconsistent with the common, broad definition of that term. *See Notice*, Merriam Webster Online, https://www.merriam-webster.com/dictionary/notice (defining notice as a "warning or intimation of something" or a "written or printed announcement"); *Notice*, Black's Law Dictionary (11th ed. 2019) (defining notice to include a "written or printed announcement"). A bill or invoice, which provides notice to a consumer of what she has been charged for and for how much, falls within this common definition. *See also, e.g.*, 42 U.S.C. § 300g-3(c)(2)(E)(i) (providing that notice to customers of drinking water standards may be given "in the first bill (if any) prepared after the date of occurrence of the violation"); 15 U.S.C. § 1681s-2(a)(7)(C) (requiring financial institutions to provide "notice" to customers of certain negative credit reporting "with any notice of default, any billing statement, or any other materials provided to the customer").

HHS also contends that "Congress left it to [the agency] to determine what 'other information'" may include only the total cost of abortion and non-abortion-related coverage. Defs.' Br. 17. However, the statute's reference to "other information specified by" HHS acts not as a delegation of discretion, as HHS contends (*id.*), but as a limitation on the HHS's authority to

require mandatory disclosure of the costs of abortion coverage beyond the disclosure specified in the statute itself.

HHS also argues that if Plaintiffs' reading of Section 1303(b)(3) is correct, the prior administration's interpretation of Section 1303, which permitted but did not require issuers to send separate bills for the abortion and non-abortion-related portions of a premium, would have also been at odds with Section 1303. Defs.' Br. 18. Plaintiffs, of course, do not challenge the earlier rule and guidance, and therefore have no obligation to defend them as valid in all respects. In any event, HHS overlooks a key distinction between the Separate-Billing Rule and the earlier regulatory regime. That regime granted issuers broad discretion to determine how to comply with the requirement for "separate payment[s]." 42 U.S.C. § 18023(b)(2)(B)(ii), (C)(ii). Except at the time of enrollment and in advertising, Section 1303(b)(3) does not limit issuers' ability to tell consumers about the cost of abortion coverage in their plans, should issuers choose to do so. Rather, it constrains HHS's ability to force issuers to provide such disclosures, either by way of "notice," *id.* § 18023(b)(3)(A), or through any "other information" specified by HHS, *id.* § 18023(b)(3)(B). Accordingly, it is entirely consistent with Section 1303(b)(3) to conclude that HHS cannot force issuers to include on each billing statement a line item identifying abortion coverage and its specific cost, but issuers may opt to provide that information to consumers if they so choose. *Cf. Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976) (recognizing that a pharmacy's ability to convey drug pricing information to consumers was entitled to First Amendment protection).

In this respect, HHS also contends that there is no conflict between the Separate-Billing Rule and the notice requirements in Section 1303(b)(3) because "any insight the policy holder gains from the separate bill" for abortion-related coverage as to the plan's coverage of such

services "is incidental to the primary purpose of the bill, which is to help ensure separate payment by the policy holder, and separate . . . issuer collection" of this payment. Defs.' Br. 17 (citing 84 Fed. Reg. at 71,694). As Plaintiffs have explained, however, a regulation that expressly requires a regulated party to do something that a statute forbids cannot be saved by reciting its asserted regulatory purpose. Pls.' Br. 36.

HHS also contends that although it recognized that the rule encouraged greater transparency, that recognition did not "transform a 'bill' into a 'notice' within the meaning of Section 1303(b)(3)(A)." Defs.' Br. 18. HHS's contention portrays Plaintiffs' position too narrowly. Plaintiffs need not show that the bill operates as a "notice" in 1303(b)(3)(A), though it clearly does. Either way, a bill is unquestionably "information specified by" HHS, pursuant to 1303(b)(3)(B), and for that reason alone cannot be required to include abortion-specific cost information.

III. HHS ADOPTED THE RULE'S OPT-OUT POLICY WITHOUT NOTICE AND AN OPPORTUNITY FOR PUBLIC COMMENT

HHS concedes that it did not provide notice to the public and an opportunity to comment before it adopted the Opt-Out Policy. *See id.* at 37–38. Instead it claims the omission was permissible because this portion of the rule is a "general statement[] of policy" exempt from notice-and-comment rulemaking under the APA. *Id.* at 38 (citing 5 U.S.C. § 553(b)(3)(A)). HHS is wrong. The Opt-Out Policy is not covered by this exemption.

To determine whether an agency action constitutes what is termed a "legislative rule" subject to notice-and-comment rulemaking, or is instead a general statement of policy exempt from this procedural requirement, courts consider whether the action has "binding effect." *Casa de Maryland*, 924 F.3d at 702 (quoting *Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec.*, 653 F.3d 1, 7 (D.C. Cir. 2011)); *see also, e.g., Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 357

(D.C. Cir. 2017). In this respect, courts assess whether the action imposes any rights and obligations, or instead "genuinely [leaves] the agency and its decisionmakers free to exercise discretion." *Clarian*, 878 F.3d at 357 (quoting *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 452 F.3d 798, 806 (D.C. Cir. 2006)). The agency's "expressed intentions," such as the agency's "own characterization of the action" and "whether the action was published in the Federal Register or the Code of Federal Regulations," are also relevant in determining whether a statement has binding effect. *Id.* (quoting *Ctr. for Auto Safety*, 452 F.3d at 806). At bottom, "[i]f it appears that a so-called policy statement is in purpose or likely effect one that narrowly limits administrative discretion, it will be taken for what it is—a binding rule of substantive law." *Guardian Fed. Savings & Loan Ass'n v. FSLIC,* 589 F.2d 658, 666–67 (D.C. Cir. 1978).

Contrary to HHS's assertions, the Opt-Out Policy does not "leave[] agency decisionmakers free to exercise their informed discretion in individual cases." *Chamber of Commerce of U.S. v. U.S. Dep't of Labor*, 174 F.3d 206, 212 (D.C. Cir. 1999) (citing *Am. Bus Ass'n v. United States*, 627 F.2d 525, 529–30 (1980)). Rather, it tells issuers that HHS "will not" take enforcement action against them for creating opt-out policies. 84 Fed. Reg. at 71,686. "The use of the word 'will' suggests the rigor of a rule, not the pliancy of a policy." *McLouth Steel Prod. Corp. v. Thomas*, 838 F.2d 1317, 1320–21 (D.C. Cir. 1988) (citing *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 947 (D.C. Cir. 1988)). With this language, the Opt-Out Policy invites "private parties [to] rely on it as a norm or safe harbor by which to shape their actions," underscoring that the policy is "binding as a practical matter." *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002) (quoting Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 Duke L.J. 1311, 1329 (1992)); *see also, e.g.*, *Chamber of Commerce*, 174 F.3d at 213 (holding that an OSHA rule was not a general statement

of policy because it left "no room for discretionary choices by inspectors in the field" and indicated that the agency would "not remove an employer from [a list of facilities not to be inspected] unless the employer fail[ed] to abide by the terms of the program").

The policy also includes other "mandatory language" that affects the rights and obligations of both issuers and enrollees. *Gen. Elec. Co.*, 290 F.3d at 383 (quoting Anthony, 41 Duke L.J. at 1329). It requires, for example, that "a policy holder's opt-out would have to be applied to all persons in the enrollment group under the policy." 84 Fed. Reg. at 71,687. And it forbids policy holders from "retract[ing] their opt-out decision and reinstat[ing] coverage of non-Hyde abortion services for that benefit year," even if they pay the abortion-related premium portion. *Id.*

Moreover, HHS published the Opt-Out Policy in the Federal Register, another indicator that it was intended to bind the agency. *Clarian*, 878 F.3d at 357. Indeed, the policy was issued as part of a comprehensive rule, the remainder of which HHS treats as binding and subject to notice-and-comment rulemaking. *See id.*

It is irrelevant, as HHS contends, that the agency could always change the Opt-Out Policy. Defs.' Br. 16. That will always be true for an agency rule, even one published in the Code of Federal Regulations, and it does not mean that the rule is non-binding. Rather, the key issue is that HHS officials would be powerless to bring an enforcement action against an issuer on the ground that it permitted opt-outs, unless and until HHS rescinds the Opt-Out Policy. For this reason, HHS's reliance (at 39) on the outcome in *Casa de Maryland*, 924 F.3d at 702, is misplaced. There, the Fourth Circuit held that a challenged memorandum did not require notice to the public and an opportunity for comment. *See id.* But it did so because the memorandum, though it "remove[d] a mechanism under which individuals could receive deferred action [from removal from the United States]," did not "curtail the Department's discretion to make deferred action available on a case-

by-case or ad hoc basis." *Id.* Here, by contrast, HHS has not left any method by which its officials could take enforcement action on a case-by-case or ad hoc basis against issuers that have complied with the Opt-Out Policy.

HHS also points to the Opt-Out Policy's requirement that issuers who allow opt-outs are expected to take steps to distinguish between an enrollee's decision to affirmatively opt out of abortion coverage and an enrollee's inadvertent non-payment of the abortion premium, suggesting that an issuer that fails to make such a distinction could face an HHS enforcement action. Defs.' Br. 15. However, HHS would base any such enforcement action on the issuer's revocation of abortion coverage to policy holders who plan to keep it (but who have inadvertently failed to pay for it), not on the issuer's willingness to permit policy holders to opt out of abortion coverage in the first place. The possibility of such an action is, therefore, irrelevant.

IV. VACATUR OF THE RULE IS THE APPROPRIATE REMEDY

HHS argues that if the Court were to grant summary judgment to Plaintiffs, it should nevertheless prohibit the rule's application only as to them, not anyone else affected by the rule. The Court should reject HHS's request, which is at odds with the APA's language, established practice in APA cases, and the remedy that Plaintiffs need to obtain full relief.

First, the plain text of 5 U.S.C. § 706 authorizes vacatur of the Final Rule. Under that provision, a reviewing court "shall . . . hold unlawful and set aside agency action" that is arbitrary, capricious, contrary to law, or adopted without procedure required by law. If a court "sets aside" a rule after review, 5 U.S.C. § 706, the rule is "annul[led]" or "vacate[d]," and therefore without effect. *Set Aside*, Black's Law Dictionary (11th ed. 2019). Despite this language, HHS argues that Section 706 is not a remedial provision, and instead sets forth only the APA's standard of review. Defs.' Br. 40. However, this proposition, for which HHS cites only a law review article, *see id.* at

40–41, is at odds with the APA's plain text. That text tells courts not just *how* to identify an unlawful rule, but what to *do* with such a rule upon judgment.

HHS also argues that, to the extent Section 706 addresses a proper remedy for an APA violation, "it does not authorize" the Court to set aside the agency action as to anyone beyond "the plaintiff in a particular case." *Id.* at 41. But the "ordinary result" is to vacate action upon a finding that it is unlawful. *Guilford Coll. v. McAleenan*, 389 F. Supp. 3d 377, 397 (M.D.N.C. 2019); *see also, e.g., United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019) (citing 5 U.S.C. § 706(2)). In such circumstances, courts generally do not simply "proscrib[e]" an unlawful rule's "application [only] to the individual petitioners." *Guilford Coll.*, 389 F. Supp. 3d at 397 (quoting *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs.*, 145 F.3d 1399, 1409 (D.C. Cir. 1998)). Rather, they issue a declaration of invalidity and call for vacatur of the rule for all purposes. *See id.* (collecting cases); *see also, e.g., Trump v. Int'l Refugee Assistance Project*, 137 S. Ct. 2080, 2088 (2017) (refusing to stay a preliminary injunction that prevented enforcement of a challenged policy "against foreign nationals who have a credible claim of a bona fide relationship with a person or entity in the United States," despite the fact that plaintiffs consisted of only two individual plaintiffs and the state of Hawaii); *Roe v. U.S. Dep't of Def.*, 947 F.3d 207, 232 (4th Cir. 2020), *as amended*, (Jan. 14, 2020) (holding in an APA case at the preliminary-injunction stage that "extending relief [nationwide] to those who are similarly situated to the litigants" is within "the equitable power of district courts").

In any event, HHS concedes that "[n]ationwide injunctions are appropriate if necessary to afford relief to the prevailing party." *Va. Soc'y for Human Life, Inc. v. Fed. Election Comm'n*, 263 F.3d 379, 393 (4th Cir. 2001) (hereinafter, "*Virginia Society*"), *overruled on other grounds by The Real Truth About Abortion, Inc. v. Fed. Election Comm'n*, 681 F.3d 544 (4th Cir. 2012); *see also,*

e.g., *Richmond Tenants Org., Inc. v. Kemp*, 956 F.2d 1300, 1305 (4th Cir. 1992) (affirming nationwide permanent injunction in a non-APA case involving plaintiffs from Maryland and Virginia, in addition to a national group of tenant organizations, and denying class certification as unnecessary).

Vacatur of the Separate-Billing Rule nationwide is essential because enjoining the rule only as to Plaintiffs would not cure the rule's deficiencies. First, although Plaintiffs are clearly injured by the rule, only issuers and exchanges are directly regulated by it, so vacatur only as to Plaintiffs would be completely unworkable. For example, PPM has provided care, including abortions, to more than 7,300 out-of-state patients since 2015, many of whom rely on a changing marketplace of insurance policies issued in Maryland and other states. Second Decl. of Karen J. Nelson Supp. Pls.' Mot. Summ. J. ¶ 3, attached hereto. PPM has served at least one patient from each state except Alaska during that time, including every state where one or more ACA exchange plans covers non-Hyde abortion services. *See id.* ¶ 4 (confirming care for, e.g., 644 patients from Delaware, 220 from New York, 96 from Massachusetts, 177 from New Jersey, 515 from the District of Columbia, 63 from Illinois, 57 from Connecticut, 166 from California, and 158 from Colorado). It would be impossible to determine all of the regulated issuers on which PPM's patients may rely for abortion or other care, *id.* ¶ 7, making full vacatur of the rule and a declaration of its invalidity the appropriate remedy here. *See Richmond Tenants Org.*, 956 F.2d at 1308–09 (upholding nationwide injunction where challenged conduct caused irreparable harm in numerous jurisdictions); *Casa de Maryland, Inc. v. Trump*, 414 F. Supp. 3d 760, 786 (D. Md. 2019) (issuing nationwide preliminary injunction where organizational plaintiff had members in three states and the District of Columbia and those members could be affected by the challenged rule when entering any port of entry in the United States), *argued*, No. 19-222 (4th Cir. May 8, 2020).

Likewise, preventing the rule's application only as to the Consumer Plaintiffs, who reside in Maryland, the District of Columbia, New Jersey, and Maine, would not prevent many of the harms they will suffer as a result of the Separate-Billing Rule. The rule will impose onerous administrative burdens on issuers around the country, some of which offer plans in multiple states, that will in turn force issuers to raise consumer premiums and in some cases drop abortion coverage altogether. 84 Fed. Reg. at 71,704–05. Even if the Court could somehow fashion a remedy that prevented the Final Rule's separate-billing and transaction requirements as applied only to the Consumer Plaintiffs, that remedy would do nothing to stop these harms, which are driven by the overall cost and burden of the rule as applied to millions of consumers' policies.

Accordingly, consistent with the APA's default remedy, vacatur of the rule and an order preventing its enforcement nationwide is "necessary to provide complete relief." *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 778 (1994) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979)); *see also, e.g.*, *Roe v. U.S. Dep't of Def.*, 947 F.3d at 232. Far from creating inefficiencies, as HHS claims, this remedy will help ensure the uniform application of a decision involving the Separate-Billing Rule, avoiding questions, for example, about how the Court could possibly fashion a limited remedy to rectify HHS's failure to conduct notice-and-comment rulemaking. (Would only some individuals be permitted to comment on a proposed rule to cure the procedural deficiency? If the agency came to a different conclusion after considering public comment, would its new rule apply only to some portion of the public? HHS does not say.) By preventing a patchwork regulatory regime, vacatur of the Final Rule would also help avoid confusion and uncertainty among regulated industries and the public.

Virginia Society and *Mayor & City Council of Baltimore v. Azar*, No. RDB-19-1103, 2020 WL 1873947 (D. Md. Apr. 15, 2020), on which HHS relies, are not to the contrary. *Virginia Society*

stands for the unremarkable proposition that the APA does not *require* vacatur of all challenged agency actions. To be sure, the APA preserves a court's "power [to] deny relief on any . . . appropriate legal or equitable ground," 5 U.S.C. § 702, but the government has provided no such ground here. And in *Mayor & City Council of Baltimore*, the Court denied a nationwide injunction where, in its view, the plaintiff had not requested such relief in its complaint or throughout the litigation. *See* 2020 WL 1873947, at *1.

To the extent that the Court nevertheless believes that some remedy less than a declaration of invalidity and vacatur of the rule in its entirety is appropriate to address the injuries of PPM and Consumer Plaintiffs, the Consumer Plaintiffs have also moved for certification of a class of consumers pursuant to Federal Rule of Civil Procedure 23(b)(2). *See* Consumer Pls.' Mot. for Class Certification and Mem. Law in Supp., ECF Nos. 40, 40-1. To the extent necessary to afford nationwide relief, Plaintiffs ask the Court to certify the consumer class and award judgment in class members' favor as well.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court (1) enter summary judgment in their favor, (2) declare the Final Rule invalid under the APA, and (3) immediately set aside the Final Rule by vacating it to prevent its enforcement.

Respectfully submitted,

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Dated: May 22, 2020

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND
(Northern Division)

PLANNED PARENTHOOD OF MARYLAND, INC., *et al.*,

Plaintiffs,

v.

ALEX M. AZAR II, Secretary of the United States Department of Health and Human Services, in his official capacity, *et al.*,

Defendants.

Case No. CCB-20-00361

SECOND DECLARATION OF KAREN J. NELSON
IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

I, Karen J. Nelson, declare and state as follows:

1. I am the President and Chief Executive Officer ("CEO") of Plaintiff Planned Parenthood of Maryland, Inc. ("PPM"). I submitted a declaration in this case in support of Plaintiffs' Motion for Summary Judgment on March 2, 2020. I provide this additional declaration to describe characteristics of PPM's patients and to demonstrate that an order from this Court vacating the Separate-Billing Rule in its entirety is necessary to prevent the harms to PPM described in my earlier declaration.

2. The facts I state here are based on my experience, my review of PPM business records, information obtained through the course of my duties at PPM, and personal knowledge that I have acquired in my over 25 years of service with affiliates of Planned Parenthood. If called and sworn as a witness, I could and would testify competently thereto.

3. Since the beginning of 2015, PPM has served more than 7,300 patients who maintained an out-of-state legal residence, including more than 1,270 out-of-state patients who obtained an abortion at one of our health centers. These patients seek our care for a number of

reasons. They may, for example, live in a nearby state and find that our health centers offer services they need and cannot obtain closer to home, attend a Maryland college or university, or be visiting Maryland for work.

4. Although many of PPM's out-of-state patients reside in surrounding states and the District of Columbia, we served at least one patient from every state except Alaska between 2015 and 2019. For example, during this time, we served 644 patients from Delaware, 220 from New York, 96 from Massachusetts, 57 from Connecticut, 177 from New Jersey, 515 from the District of Columbia, 63 from Illinois, 28 from Washington State, 166 from California, 158 from Colorado, 12 from New Hampshire, 6 from Rhode Island, 18 from Vermont, 13 from Maine, 15 from Oregon, and 18 from Montana.

5. PPM directly sought health insurance reimbursement for some of these patients' care. Patients whose out-of-state insurers would have covered our services but with whom we do not have an established reimbursement relationship (exclusive of Medicaid and Medicare patients) could have independently sought reimbursement for their out-of-pocket expenses for our care.

6. Like all health care providers, the composition of PPM's patient population necessarily changes over time.

7. Although PPM is able to identify some portion of its patient population that relies on a state-based Affordable Care Act exchange, to my knowledge that is not possible for all patients and plans.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on May 22, 2020.

Karen J. Nelson