

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-01630 (JEB)

**PLAINTIFFS' REPLY IN SUPPORT OF MOTION
TO LIFT STAY OF PROCEEDINGS**

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PRELIMINARY STATEMENT

The stay of this case should be lifted. An open-ended stay is not warranted. Plaintiffs agreed to stay this litigation for 90 days (February 16, 2021 to May 14, 2021) while the new administration reviewed the litigation and challenged rule and determined how it wished to proceed, after which the parties agreed to submit a “proposal for further proceedings” in this case. After counsel for Defendants disclosed in May 2021 that HHS preferred a prolonged stay as it intended to initiate a new rulemaking, Plaintiffs expressed concern and opposition to a prolonged stay due to the ongoing harms caused by the 2020 Rule but agreed to an additional 30-day stay to allow time for Defendants to evaluate measures that would ameliorate these harms while they engaged in rulemaking, such as the issuance of interim final rules. At no point have Plaintiffs ever agreed to stay the case indefinitely so that HHS could engage in a full notice-and-comment rulemaking. Put simply, Defendants are taking advantage of Plaintiffs’ extension of comity to allow a new administration time to get its bearings and are now trying to use that accommodation to deny Plaintiffs their day in court. The Court should reject this gamesmanship.

An indefinite stay is not warranted, appropriate, or just, in any event. Defendants do not cite any case in which a court stayed a challenge to a final rule over the petitioner’s objections based on an agency’s intent to engage in a new rulemaking. The authority on which they rely is inapposite. Cases in which courts found it appropriate to remand so an agency could reconsider the results of an adjudication do not support staying a challenge to a final rule with nationwide application and import indefinitely (and allowing the rule’s harms to continue) until an agency initiates and then completes a new notice-and-comment rulemaking. Next, the Court is not bound by unpublished orders that granted the EPA’s motions to stay several appeals, and, in any event, those motions were not opposed by the petitioners in those cases, who were protected by stays or delayed effective dates. And although courts in this Circuit have, on occasion, found that ongoing

rulemaking proceedings rendered challenges to existing rules unripe, the agency proceedings in those cases were substantially more developed than HHS's nascent intent to engage in rulemaking under Section 1557; the risk of ongoing harm to the petitioners was negligible or non-existent (*e.g.*, one regulation had a safe harbor provision); the scope of the rulemaking was known; and there were external factors requiring rulemaking to be completed on a certain schedule. No such safeguards exist here.

More importantly, however, the balance of harms tilts significantly in favor of Plaintiffs. Defendants offer no meaningful response to Plaintiffs' detailed explanation regarding how the 2020 Rule is harming and will continue to harm Plaintiffs, their patients, and their members. They instead suggest that Plaintiffs are not prejudiced because they may ultimately obtain the relief they seek through the rulemaking process, and because this Court already addressed the provisions that remain in effect in its ruling on Plaintiffs' motion for preliminary relief. Neither argument demonstrates a lack of prejudice—particularly where Defendants admit that HHS itself has “substantial and legitimate concerns” with the rule that Plaintiffs are challenging in this proceeding. *Opp.* at 1 (ECF No. 75). On the other side of the scale, Defendants have not demonstrated that allowing this litigation to proceed will impose an unreasonable burden on agency counsel at HHS that warrants staying this case entirely until HHS issues both a notice of proposed rulemaking and a final rule.

The stay should be lifted.

I. PLAINTIFFS DID NOT AGREE TO STAY THE CASE UNTIL THE AGENCY COMPLETED A YET-TO-BE-ANNOUNCED RULEMAKING

Plaintiffs have never agreed, as Defendants have suggested, to ‘hold the case in abeyance pending reconsideration by the agency.’ *Opp.* at 10; *see also id.* at 1, 4, & 7.

In their February 2021 submission, the parties asked the Court to “stay further district court proceedings pending the new administration’s *review* of this litigation and the rule being challenged,” and proposed a May 14, 2021 deadline for the parties to “file a joint status report . . . apprising the Court of the status of the matter and *submitting a proposal for further proceedings.*” Joint Motion ¶¶ 6-7 (ECF No. 70) (emphasis added). Plaintiffs certainly did not agree and could not have agreed that the stay should remain in effect until the completion of full notice-and-comment rulemaking. At that point, HHS had not yet resolved to pursue that course of action. Plaintiffs were first informed on May 11, 2021 that HHS had “determined that it intends to initiate a rulemaking.” Joint Status Report at 1-2 (ECF No. 71).

Plaintiffs agreed to a brief 90-day stay based on the understanding that, after the 90 days, the parties would engage in substantive discussions regarding a schedule for further proceedings in this litigation. Plaintiffs would not have signed on to the February 2021 submission if they had known that the only “further proceedings” that Defendants would discuss after this 90-day pause would be further deadlines to submit status reports.

The parties selected the May 14, 2021 deadline deliberately on grounds that it fell two weeks after a deadline for agency heads to “consider whether to . . . promulgate new agency actions, as necessary to fully implement statutes that prohibit sex discrimination . . .” Exec. Order 13988: Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, 86 Fed. Reg. 7,023, 7023 (Jan. 25, 2021). The joint motion noted expressly that the parties were building in “two weeks to confer” after this deadline. Joint Motion ¶ 7 (ECF No. 70). If Plaintiffs already had agreed to stay the case indefinitely pending some as-yet-to-be-announced plan to engage in rulemaking, there would be no need to allow for two weeks to confer regarding a “proposal for further proceedings.”

Defendants fault Plaintiffs for not insisting that the joint motion specify that the stay would expire on the same date that the parties submitted their “proposal for further proceedings.” They compare the joint motion in this case with the joint motion filed in the *Chinatown Service Center* Section 1557 case, which expressly requested that the stay expire on the parties’ agreed-to July 16, 2021 deadline to “file a joint status report . . . apprising the Court of the status of agency proceedings and submitting a proposal for further proceedings.” Joint Motion, *Chinatown Serv. Ctr. et al. v. U.S. Dep’t of Health & Human Servs., et al.*, No. 1:21-cv-00331-JEB (D.D.C. May 26, 2021), ECF No. 18 at 4. The *Chinatown* plaintiffs’ insistence on an expressly time-limited stay comes as no surprise. The parties in that case filed their joint motion on May 26, 2021, and the plaintiffs specifically cited portions of the May 14, 2021 joint status report filed in this case in explaining why they were agreeing only to a “limited duration stay.” *Id.* at 2-3. Had Plaintiffs anticipated Defendants’ bad-faith refusal to propose anything other than future status-report deadlines, they would have insisted on including similar language in the joint motion that specified that the stay would expire when the parties submitted their “proposal for further proceedings.”

And lest there be any doubt, the parties’ communications make clear that Plaintiffs were only agreeing to a limited stay to allow the new administration to “review [] this litigation and the rule being challenged.” Joint Motion ¶ 6 (ECF No. 70). For example, on February 10, 2021, Plaintiffs agreed to “not oppose moving to stay the proceedings in the district court and the court of appeals *thru May 14, 2021* in light of the EOs noted below.” Ex. 1, Feb. 10, 2021 Email from O. Gonzalez-Pagan (emphasis added). After being advised on May 11, 2021 that HHS preferred a prolonged stay as it intended to engage in a new rulemaking, Plaintiffs expressed concern and opposition to a prolonged stay due to the ongoing harms caused by the 2020 Rule but agreed to an additional 30-day stay to allow Defendants to evaluate measures that would ameliorate these harms

while they engaged in rulemaking, such as the issuance of interim final rules. As Plaintiffs explained in their portion of the parties' May 14, 2021 joint status report:

[I]n appreciation of the government's announced intentions and in the spirit of cooperation, Plaintiffs met and conferred with Defendants on May 11 and 13, 2021. During the meet-and-confer, Plaintiffs suggested to Defendants a proposed course of action that would ameliorate at least some of the harms from the Revised Rule's provisions currently in effect while allowing time for Defendants to engage in rulemaking. Plaintiffs also inquired whether there are alternatives that would allow Defendants to engage in rulemaking while addressing the harms caused by the Revised Rule's provisions currently in effect. Defendants noted that they needed time to address these points.

Accordingly, and in light of the above, Plaintiffs agree that this case should remain stayed for the limited period of 30 days to permit Defendants to explore alternatives and provide details of their intended rulemaking.

Joint Status Report at 6 (ECF No. 71). Plaintiffs made clear, however, that they "believe that an indefinite and/or prolonged stay of proceedings before this Court is inappropriate." *Id.* at 3.

Put simply, Defendants seek to take advantage of Plaintiffs' willingness to *temporarily* pause this litigation to allow a new administration to find its sea legs by suggesting that Plaintiffs have thereby waived any objection to staying this case indefinitely. Such gamesmanship should be rejected, not only because it disincentivizes litigants from agreeing to such accommodations in the future, but also because an indefinite stay is not warranted, appropriate, or just under the circumstances of this case.

II. THE STAY SHOULD BE LIFTED

In any event, Defendants' opposition brief fails to set out a sufficient basis to continue to stay this litigation while HHS promulgates a Notice of Proposed Rulemaking that is still many months away, collects and reviews comments by the public, and issues a final rule—all while the 2020 Rule continues to cause harm.

A. The authorities on which Defendants rely do not support staying this litigation until HHS issues a new Final Rule.

Defendants do not point to a single judicial opinion in which a court stayed a proceeding over the petitioner’s objection because the agency intended to engage in rulemaking of undefined scope in the future. Rather, they rely on (i) a few appeals from adjudications that were remanded for reconsideration by the agency; (ii) unpublished orders that were issued based on unopposed motions; (iii) a handful of decisions that found challenges to existing rules unripe in light of ongoing rulemaking that had a sufficiently clear and defined scope; and (iv) completely inapposite cases that apply other administrative law doctrines (*e.g.*, unreasonable delay and exhaustion). As set out below, these citations do not support staying this case until HHS issues a new final rule.

1. This case is nothing like those in which courts remanded appeals of agency adjudications to permit the agencies to reconsider the challenged findings.

In arguing that an indefinite stay is appropriate, Defendants rely principally on a line from a 1962 D.C. Circuit decision that states that, “[w]here an agency seeks to reconsider its action, it should move the court to remand or to hold the case in abeyance pending reconsideration by the agency.” *Anchor Line Ltd. v. Fed. Maritime Comm’n*, 299 F.2d 124, 125 (D.C. Cir. 1962) (quoted in *Ethyl Corp. v. Browner*, 989 F.2d 522, 524 n.3 (D.C. Cir. 1993); *see also* Opp. at 1, 4, & 10 (quoting *Anchor Line* or *Ethyl Corp.*). Such a request “may be granted only when the agency intends to take further action with respect to the original agency *decision* on review.” *Limnia, Inc. v. U.S. Dep’t of Energy*, 857 F.3d 379, 386 (D.C. Cir. 2017) (emphasis added). However, where the agency seeks remand “to reconsider its previous position” (as opposed to in response to a change in circumstances outside of its control, such as new legislation), a court “must ‘consider whether remand would unduly prejudice the non-moving party,’ and, contrary to Defendants’

suggestion (Opp. at 10), it may not limit its consideration to whether the request is “frivolous or made in bad faith.” *Util. Solid Waste Activities Grp. v. EPA*, 901 F.3d 414, 436 (D.C. Cir. 2018).

Defendants omit a key piece of context when relying on *Anchor Line, Ethyl Corp.*, and *SKF USA* to argue that the Court should hold this proceeding in abeyance pending HHS’s “reconsideration” of the 2020 Rule. *See* Opp. at 6 & 10. Unlike the instant challenge to a final rule with nationwide application, those appeals were all initiated by petitioners who were unhappy with the results of agency adjudications that specifically concerned those parties.¹ *See Anchor Line*, 299 F.2d at 125 (Federal Maritime Commission’s determination that petitioners had violated § 15 of the Shipping Act); *Ethyl Corp.*, 989 F.2d at 523 (EPA’s denial of an application for a waiver from a general ban on certain fuel additives); *SKF USA Inc. v. United States*, 254 F.3d 1022, 1025 (Fed. Cir. 2001) (Court of International Trade’s inclusion of a loss that a company incurred in selling a subsidiary in the Court’s calculation of the company’s general and administrative expenses).² The petitioners were not prejudiced by remanding the matters to the agencies for reconsideration because (i) the rulings had no practical impact while under

¹ “Not only has Congress built the procedural provisions of the Administrative Procedure Act, 5 U.S.C. s 551 et seq. (1970), around this difference in agency functions, but also the Supreme Court has repeatedly emphasized that there is a recognized distinction in administrative law between proceedings for the purpose of promulgating policy-type rules or standards, on the one hand, and proceedings designed to adjudicate disputed facts in particular cases on the other.” *Indep. Bankers Ass’n of Ga. v. Bd. of Governors of Fed. Rsrv. Sys.*, 516 F.2d 1206, 1215 (D.C. Cir. 1975) (citing *United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224, 245 (1973)).

² Defendants also cite this Court’s decision in *Liff* repeatedly. *Liff* concerned an entirely different question of whether a stay of district court proceedings should remain in effect while the government appealed the denial of qualified immunity. *See Liff v. Off. of Inspector Gen., Dep’t of Labor*, No. 14-1162 (JEB), 2016 WL 4506970, at *2 (D.D.C. Aug. 26, 2016). The Court’s decision turned on whether it had jurisdiction over issues that did not overlap with the issue on appeal. *Id.* In any event, the case did not involve a challenge to a rulemaking. The complaint was filed by a veteran who alleged that federal agencies improperly terminated an outstanding task order and constructively disbarred him from engaging in future government-contracting work. *See Liff v. Off. of Inspector Gen., Dep’t of Labor*, 156 F. Supp. 3d 1, 9 (D.D.C. 2016).

reconsideration, and (ii) the petitioners could obtain complete relief if the agencies reversed course.

In contrast, Plaintiffs have challenged a formal rulemaking affecting not only Plaintiffs, their patients, and their members, but also countless others. Reconsideration cannot afford complete relief, because Plaintiffs seek vacatur of this existing rule, or portions thereof. Although it is theoretically possible that HHS could address every issue that Plaintiffs challenge in their anticipated rulemaking, nothing requires them to do so.

In addition, the 2020 Revised Rule remains in effect, except for those portions that have been enjoined, and thereby causes ongoing harms. The Court has already recognized that Plaintiffs are injured by HHS's decision to eliminate certain provisions in the 2016 Rule (*e.g.*, the prohibition on categorical exclusions and certain language-access protections), and that they therefore have standing to challenge these aspects of the rule. *See Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 485 F. Supp. 3d 1, 29-31 (D.D.C. 2020). Plaintiffs have likewise set forth how they are harmed by the Revised Rule's narrowing of covered entities. *See* Motion at 15-16 (ECF No. 74). A federal court in Boston found such harms sufficient to afford standing to a similarly situated group of healthcare providers and advocates that "plausibly allege[d] that the narrowed scope of covered entities will result in more patients seeking their services and reduced insurance reimbursements, which 'will consume Plaintiff Healthcare Facilities' budgets, force Plaintiff Healthcare Advocates to divert limited resources to help people navigate barriers to care, and make it harder for individuals to access care." *Boston Alliance of Gay, Lesbian, Bisexual & Transgender Youth v. U.S. Dep't of Health & Hum. Servs.*, No. CV 20-11297-PBS, 2021 WL 3667760, at *9 (D. Mass. Aug. 18, 2021) (hereinafter "*BAGLY*").

2. The circumstances here are not like those in which courts granted the EPA's unopposed motions to hold appeals in abeyance while it reconsidered Obama-era Clean Air Act regulations.

Defendants cite several unpublished orders in which federal appellate courts agreed to hold proceedings in abeyance while the Trump administration reconsidered Obama-era regulations promulgated under the Clean Air Act. *See* Opp. at 11. The orders are all distinguishable, and they have no persuasive value here.

In all three appeals, the petitioners did not oppose (or took no position with respect to) staying the appeal until the Environmental Protection Agency completed its reconsideration of the challenged rule, including any new rulemaking. *See, e.g.*, Notice and Motion, *West Virginia v. E.P.A.*, No. 15-1363 (D.C. Cir. Mar. 28, 2017), Doc. #1668274 at p. 8 (regulated entities did not oppose the EPA's motion to stay appeal of consolidated challenges to Obama-era Clean Power Plan rulemaking); Status Report and Motion, *Arkansas v. E.P.A.*, No. 16-4270 (8th Cir. Dec. 15, 2017), Doc. #4611165 at pp. 5-6 (states and regulated entities did not oppose or took no position with respect to motion to hold appeal in abeyance "pending completion of administrative proceedings to replace all provisions" of the challenged regulation); Motion, *Dalton Trucking, Inc. v. EPA*, No. 13-74019 (9th Cir. May 5, 2017), Doc. # 10423672 at p. 2 (petitioners did not oppose motion to continue oral argument in light of ongoing review of the previous administration's Off-Road Diesel Decision).

It is not surprising that none of the regulated entities that filed these appeals opposed the EPA's motion to hold the appeals in abeyance. The U.S. Supreme Court had already stayed the Clean Power Plan, and, regardless, the Plan would not require any action by any entity until "2022 at the earliest." Notice and Motion, *West Virginia v. E.P.A.*, No. 15-1363 (D.C. Cir. Mar. 28, 2017), Doc. #1668274 at p. 8. In the *Arkansas* appeal, the EPA agreed not to oppose petitioners' motion to stay challenged portions of a Clean Air Act regulation, and thus paved the way for

petitioners to agree to hold the appeal in abeyance for a prolonged period. *See* Status Report and Motion, *Arkansas v. E.P.A.*, No. 16-4270 (8th Cir. Dec. 15, 2017), Doc. #4611165 at p. 6 (“Given EPA’s initiation of reconsideration of portions of the Final Rule . . . , EPA does not oppose the requested stay of the portions of the Final Rule establishing NOx emission limits for the six power plant facilities and SO2 emission limits for the White Bluff and Independence power plant facilities.”).

Here, in contrast, Plaintiffs oppose staying this litigation indefinitely while the agency engages in its anticipated rulemaking, and they have identified harms that will continue as long as the non-enjoined provisions of the 2020 Rule remain in effect. These orders have no persuasive value under these circumstances.

3. This case does not involve the factors that have led courts to find challenges to existing rules unripe due to ongoing rulemaking of a clear and definite scope.

Defendants also point to a handful of cases in which courts in this Circuit held that an agency’s initiation of a new rulemaking rendered a challenge to an existing rule unripe because it meant that the reasoning expressed in a final rule was only “tentative.” *See* Opp. at 12; *Am. Petroleum Inst. v. E.P.A.*, 683 F.3d 382 (D.C. Cir. 2012); *Belmont Abbey College v. Sebelius*, 878 F. Supp. 2d 25 (D.D.C. 2012). These decisions made clear that such a finding is the exception rather than the rule, and they confirm that, as a general matter, an agency cannot “stave off judicial review of a challenged rule simply by initiating a new proposed rulemaking that would amend the rule in a significant way.” *Am. Petroleum*, 683 F.3d at 388. “If that were true, a savvy agency could perpetually dodge review.” *Id.* Although these decisions ultimately found that the circumstances supported a finding that a challenge had been rendered unripe, the factors that supported those determinations are not present here.

In *American Petroleum*, the D.C. Circuit held that the EPA’s initiation of a new rulemaking rendered a challenge to an existing rule unripe because the agency’s willingness to reconsider the issue under review meant that its position on that issue was “tentative.” *Id.* at 387-88. The court pointed to two factors in particular that led it to believe that there was little “risk of agency abuse”: (1) the agency had already issued a notice of proposed rulemaking that suggested a “complete reversal of course on EPA’s part”; and (2) the “happening or timing” of final action on the 2011 proposed rule was “not within the discretion of or controlled by the agency” because the proposed rule was issued as part of a settlement with the Sierra Club that “require[d] EPA to take final action concerning the proposed rulemaking by December 31, 2012.” *Id.* at 388-89.³

In *Belmont Abbey College v. Sebelius*, 878 F. Supp. 2d 25 (D.D.C. 2012), this Court applied the framework set out in *American Petroleum* to a challenge by a private Catholic college to federal regulations that implemented a provision of the Affordable Care Act requiring employers to offer health insurance plans that allow employees to obtain certain forms of contraception without a co-pay. The college filed its complaint in November 2011, seeking judicial review of what was then an interim final rule. The agencies issued a final rule in February 2012, and announced simultaneously that they “inten[ded] to develop alternative means of providing contraceptive services free of charge to employees of non-exempt, non-grandfathered organizations with religious objections to contraceptive coverage.” *Id.* at 31. In March 2012, the agencies issued an Advance Notice of Proposed Rulemaking (ANPRM) that “formally declar[ed] their intention to amend the final regulations” and “present[ed] questions and ideas” about how to accommodate

³ Defendants cite but do not discuss a 2003 D.C. Circuit decision holding that a petition was not ripe for review because, in September 2002, the EPA issued a notice that proposed amending the challenged regulations. *See Utility Air Reg. Grp. v. E.P.A.*, 320 F.3d 272, 278-79 (D.C. Cir. 2003) (Opp. at 11-12). The court also held that the petitioner lacked standing. *Id.* at 277-78.

non-profit religious organizations' objections to covering contraceptive services. *Id.* The notice called for a 90-day comment period that would then lead the issuance of a Notice of Proposed Rulemaking. *Id.* In April 2012, the agencies moved to dismiss on grounds that the ongoing agency actions meant that the college lacked standing and its challenge was not ripe.

The Court agreed on both counts. As to standing, it found that the college was not threatened with an "imminent" injury because the agencies had "published their plan to amend the rule to address the exact concerns Plaintiff raises in this action," and had "stated clearly and repeatedly in the Federal Register that they intend to finalize the changes before the enforcement safe harbor ends." *Id.* at 36. As to ripeness, the Court looked to the D.C. Circuit's analysis in *American Petroleum* and considered "whether the ANPRM in conjunction with Defendants' promises to issue amended regulations render the 'final' rules tentative for purposes of the ripeness inquiry." *Id.* at 38. It determined that the agencies' "position on the policy at issue remains indeterminate" in light of its consideration of the policy in connection with the ANPRM. *Id.* at 39. It noted the concern expressed in *American Petroleum* about allowing the agency to avoid review, and stated that, although the circumstances "are slightly less favorable to the agency, they nevertheless counsel the same result." *Id.* at 40. The Court observed:

The ideas and questions raised in the ANPRM appear to be the product of significant research and deliberation, *see* 77 Fed. Reg. 16501-01 (citing findings of actuaries and experts and referencing consultations with interested parties), and although there is not an externally imposed deadline on the rulemaking as there was in *American Petroleum*, the expiration of the enforcement safe harbor operates in a similar manner.

*Id.*⁴

⁴ Defendants also cite *Occidental Chemical Corp. v. F.E.R.C.*, 869 F.2d 127 (2d Cir. 1989), suggesting that it stands for the proposition that a court should not "intervene" when there is a "pending rulemaking process." *Opp.* at 12. But *Occidental* did not involve a challenge to an existing rule. The appellants sought review of an order entered in a FERC adjudication that concerned states' authority to charge certain rates. *Id.* at 128. "In recognition of the impact that

The approach taken in these cases is the exception, not the rule. Just this week, a federal district court in Massachusetts rejected HHS's contention that a similar challenge to the 2020 Revised Rule is not ripe due to the agency's intention to engage in rulemaking:

As to the provisions for which the Court finds standing, each is ripe for review. . . . Although HHS has stated its intention to "initiate a [new] rulemaking proceeding on Section 1557," it has not yet done so at this juncture. See Dkt. 59 at 18 (alteration in original). Plaintiffs have shown changes in coverage by several insurers and face a risk of economic injury from reduced reimbursements now.

BAGLY, 2021 WL 3667760, at *14. And in *Wyoming v. Zinke* (which Defendants cite at Opp. at 11), the Tenth Circuit held that *American Petroleum* did **not** support holding an appeal in abeyance indefinitely while the Bureau of Land Management reconsidered the regulation at issue. *See Wyoming v. Zinke*, 871 F.3d 1133, 1143-44 (10th Cir. 2017) (cited in Opp. at 11).

In any event, the facts of this case are distinguishable from those on which the courts relied in *American Petroleum* and *Belmont Abbey*. The 2020 Revised Rule is already in effect, unlike the rule in *Belmont Abbey*, which could not be applied to the plaintiffs due to the safe harbor provision. The agency is still many months away from issuing a Notice of Proposed Rulemaking. It has not issued an Anticipated Notice of Proposed Rulemaking. Therefore, neither the Court nor Plaintiffs can be confident that the rulemaking will address the "exact concerns" that these Plaintiffs have raised. *See Belmont Abbey*, 878 F. Supp. 2d at 36. The declaration submitted by the Acting Director of the Office of Civil Rights confirms that HHS stated its intent to revise the rule in the 2021 Spring Unified Agenda of Federal Regulatory and Deregulatory Actions. *See*

its ruling would have and in view of the desire of many in the industry to be heard," FERC commenced a rulemaking to address the issue covered by the order. *Id.* At the same time, it stayed the order from going into effect. *Id.* The Second Circuit held that a challenge to the order was not ripe because a stayed order does not constitute final agency action or have any practical effect on the petitioner. *Id.* at 129. Here, the 2020 Revised Rule remains in effect except as to the provisions that have been enjoined.

Frohboese Decl. ¶ 7 (ECF No. 75-1).⁵ But merely announcing an intent to reconsider the rule does not confirm the scope of any future rulemaking. And, of course, there are no external constraints that would require the agency to complete its rulemaking by a date certain, unlike the specific deadlines that the courts found significant in *American Petroleum* and *Belmont*.

Perhaps because the circumstances here differ materially from those in *American Petroleum* and *Belmont*, Defendants invoke cases in which litigation was stayed for multiple years to allow other litigation to proceed. *See* Opp. at 13-14. The fact-dependent holdings as to whether those particular stays were appropriate have no bearing on whether this case should remain stayed over Plaintiffs' objection based on HHS's stated intention to reconsider the 2020 Rule challenged in this litigation through a future rulemaking.

Defendants also misplace their reliance on *Mexichem Specialty Resins, Inc. v. E.P.A.*, 787 F.3d 544 (D.C. Cir. 2015) to argue that the court should stay this case indefinitely pending the completion of HHS's forthcoming rulemaking. *See* Opp. at 10, 14. *Mexichem* did not involve the question of whether it was appropriate to stay a challenge to an existing rule so that the agency could "reconsider" the rule through future notice-and-comment rulemaking. Rather, the case addressed whether the agency's delay in taking a final action violated the petitioners' "'right to timely decisionmaking' implicit in the agency's regulatory scheme." *Id.* at 554. The petitioners claimed that the EPA had "functionally denied their petitions for reconsideration" where it granted their request for reconsideration in September 2012 and did not anticipate completing its review until April 2016. *Id.* The court held that the petitioners had "failed to make the requisite showing

⁵ HHS opened a rulemaking docket that states that the "proposed rulemaking would propose changes to the 2020 Final Rule implementing section 1557 . . ." but provides no other details. *See* Exhibit 2 (screen shot of RIN 0945-AA17, OFF. INFO. & REG. AFF., <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202104&RIN=0945-AA17> (last visited Aug. 20, 2021) (RIN 0945-AA17 in the Spring 2021 Unified Agenda)).

that EPA has engaged in unreasonable delay.” *Id.* Here, Plaintiffs do not claim that HHS has violated someone’s rights by taking too long to promulgate a rule. The question here is whether an existing challenge to a final rule should be stayed until HHS issues a new rule. *Mexichem* has no bearing on that question.

4. Defendants’ remaining authorities involve administrative law doctrines that have no bearing on the issue before the Court.

The remainder of the authorities Defendants cite applied general administrative law doctrines that have no bearing on the issues presented here. *See McCarthy v. Madigan*, 503 U.S. 140, 145 (1992) (superseded by statute) (Opp. at 11, 12) (noting that a virtue of the exhaustion requirement is that requiring petitioners to exhaust administrative remedies before seeking judicial review may allow the agency to correct its own errors); *Toilet Goods Ass’n v. Gardner*, 387 U.S. 158 (1967) (Opp. at 12) (examining pre-enforcement challenge to FDA regulations that permitted the agency to suspend certifications if a manufacturer refused to permit FDA employees access to manufacturing facilities, and holding that issue would be better addressed in the context of a specific enforcement action); *Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43 (D.C. Cir. 1999) (Opp. at 12) (holding that a challenge to a NEPA action was not yet ripe because the Bureau of Land Management had yet to issue any leases, while a claim that the Forest Service had violated its own regulations was ripe because the agency had already “implemented the procedures” that the petitioner sought to challenge); *Pub. Citizen Health Research Grp. v. Comm’r, F.D.A.*, 740 F.2d 21 (D.C. Cir. 1984) (Opp. at 12) (holding that the FDA’s “preliminary” findings as to labeling were not reviewable because the rulemaking process was ongoing, but remanding to the district court for a determination regarding whether the FDA had “unreasonably delayed” resolution of the issue); *United States v. Morgan*, 313 U.S. 409, 422 (1941) (Opp. at 10) (holding that it was inappropriate for an administrative law judge to permit the Secretary to be deposed, just as it would

be inappropriate to require an Article III judge to sit for a deposition); *Nat'l Ass'n of Home Builders v. E.P.A.*, 682 F.3d 1032 (D.C. Cir. 2012) (Opp. at 11) (holding that the E.P.A.'s change of course under a new administration was not arbitrary and capricious).

B. Plaintiffs are suffering and will continue to suffer concrete harms while the stay remains in effect.

Defendants offer no meaningful response to Plaintiffs' explanation that they and their patients and members will continue to suffer tangible, concrete harms as long as the 2020 Rule remains in effect. *See* Mot. at 14-17 (ECF No. 74). They instead point to the fact that these harms may be addressed by the future issuance of a more favorable rule, rely on this court's denial of preliminary relief with respect to certain claims, and suggest that Plaintiffs can bring individual enforcement actions against persons or entities that commit wrongful acts. Opp. at 14. None of these reasons is sufficient.

Defendants first contend that Plaintiffs will not be prejudiced because the yet-to-be-promulgated rule may address the issues that gave rise to their Complaint. They do not cite a single case in which a court has held that a party is not prejudiced by ongoing harm merely because that harm may be addressed at some point in the future. Defendants assert, incorrectly, that "Plaintiffs . . . must 'demonstrat[e] that the agency will certainly, or even probably, deny relief.'" Opp. at 15 (quoting *Randolph-Sheppard Vendors of Am. v. Weinberger*, 795 F.2d 90, 106-07 (D.C. Cir. 1986)). The case on which Defendants rely for this proposition (*Randolph-Sheppard Vendors*) involved the entirely different issue of whether it was appropriate to treat agency action as final where the petitioner contended that arbitrating a dispute with the Department of Education would be futile. The court reasonably held that the petitioner was required to demonstrate a near certainty that the agency would ultimately deny relief before it could be excused from exhausting its

administrative remedies. *Id.* at 106-07. Defendants do not cite any case that extends this principle to a motion to hold a case in abeyance in light of a forthcoming rulemaking.

Defendants also point to a case in which the D.C. Circuit observed that “[a]dministrative reconsideration is a more expeditious and efficient means of achieving an adjustment of agency policy than is resort to the federal courts.” *Opp.* at 15 (quoting *B.J. Alan Co. v. I.C.C.*, 897 F.2d 561, 562 n.1 (D.C. Cir. 1990)). *B.J. Alan* discussed that proposition when rejecting the argument that the Interstate Commerce Commission lacked jurisdiction to reopen proceedings once a petition was filed in the D.C. Circuit. 897 F.2d at 562 n.1. The D.C. Circuit made this observation originally in a decision involving whether a petitioner could bypass a statutory process for seeking agency reconsideration of a ratemaking decision. *See Pennsylvania v. I.C.C.*, 590 F.2d 1187, 1194 (D.C. Cir. 1978). Neither of these cases supports the conclusion that Defendants urge this Court to draw—*i.e.*, that Plaintiffs are not prejudiced by an indefinite stay because an administrative remedy is ultimately to be preferred to a judicial remedy. And, again, remanding an appeal from an adjudication or holding it abeyance so that the agency can reconsider its position is an entirely different animal than staying a challenge to an existing, in-effect regulation until the agency issues an entirely new rule through a full notice-and-comment process.

Defendants next suggest that Plaintiffs are not prejudiced because the Court found in its ruling on Plaintiffs’ motion for preliminary relief that Plaintiffs were unlikely to succeed with respect to certain claims and lacked standing to pursue others. *See Opp.* at 16. They are wrong for two reasons. First, Defendants ignore that the Court found that Plaintiffs had carried their preliminary burden to establish standing to challenge portions of the Revised Rule that are not enjoined, such as the elimination of the prohibition on categorical exclusions and notice and tagline requirements. Moreover, the question of standing as to other parts of the Revised Rule, such as the

narrowing of covered entities, is a live question before the Court. Plaintiffs submitted additional declarations supporting their claim to standing when opposing Defendants' motion to dismiss, and also pointed to evidence that was already in the record that the Court may have overlooked in its ruling on the motion for preliminary relief. *See* Nelson Decl. (ECF No. 66-2); Valentin Pedroza Decl. (ECF No. 66-3); *see generally* Opp. to Mot. to Dismiss at 3-17 (ECF No. 66). As the *BAGLY* court recognized, "the narrowed scope of covered entities will result in more patients seeking their services and reduced insurance reimbursements, which 'will consume Plaintiff Healthcare Facilities' budgets, force Plaintiff Healthcare Advocates to divert limited resources to help people navigate barriers to care, and make it harder for individuals to access care.'" *BAGLY*, 2021 WL 3667760, at *9.

Second, as Defendants are well aware, a court's determination that a plaintiff is unlikely to succeed on some claims based on a preliminary injunction record does not mean that the plaintiff will not ultimately prevail on such claims during merits briefing. It is well established that an "order denying preliminary relief . . . 'does not constitute the law of the case.'" *Belbacha v. Bush*, 520 F.3d 452, 458 (D.C. Cir. 2008) (quoting *Berrigan v. Sigler*, 499 F.2d 514, 518 (D.C. Cir. 1974)); *see also Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981) ("A party . . . is not required to prove his case in full at a preliminary injunction hearing[,] . . . and the findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits."). Defendants do not cite any case that holds that a ruling on a motion for preliminary relief has any bearing on whether a case should be stayed, because they cannot.

Finally, Defendants assert that Plaintiffs are not prejudiced because "the Court's stay does not deprive Plaintiffs of numerous avenues for seeking relief directly against the participants in the health system that might cause them harm." Opp. at 14. Defendants fail to provide any further

reasoning on this point, and, in any event, the solution they propose is inadequate. By way of example (and as noted above), Plaintiffs suffer ongoing economic harms (which cannot be recouped) due to the 2020 Rule eliminating provisions of the 2016 Rule that prohibited insurers from categorically barring coverage for gender-affirming care. “It is by no means speculative to conclude that, under the 2020 Rule, certain insurers will deny reimbursement for treatment they previously covered.” *Whitman-Walker Clinic*, 485 F. Supp. 3d at 29. The Plaintiffs in this case include healthcare providers who are not in a position to sue insurance companies when coverage is denied. The best recourse for healthcare providers to stave off the predictable effects of insurance carriers denying reimbursement is to reinstate the 2016 Rule’s prohibition on categorical exclusions of gender-affirming care.

C. Any future need to involve HHS counsel in litigation does not impose the sort of burden that would warrant an indefinite stay.

Defendants contend that they will be harmed if this litigation is allowed to proceed because the “ongoing litigation would likely interfere with HHS’s rulemaking, as HHS would have to prioritize pending litigation deadlines.” *Opp.* at 17. They claim that HHS attorneys have provided “extensive assistance” to the attorneys with the U.S. Department of Justice in this litigation, and contend that HHS counsel will continue to be required to do so if this case proceeds. *Id.* As support for their arguments, Defendants offer only a single, terse sentence in the declaration by the Acting Director of the Office of Civil Rights that “[t]his litigation, as well as other litigation challenging the 2020 Rule, has diverted HHS’s resources in focusing on rulemaking.” Frohboese Decl. ¶ 14 (ECF No. 75-1). Respectfully, this statement does not provide a sufficient basis to stay these proceedings indefinitely. The declaration does not explain which resources have been diverted or how and why this diversion of resources has occurred. Nor does the Acting Director

state that HHS counsel are actively assisting the Department of Justice in this litigation, let alone offering the extensive support described in Defendants' opposition brief.

Defendants substantially overstate the burden on agency counsel as well as the extent to which allowing this litigation to proceed will hamper HHS's rulemaking efforts. Notably, Defendants have already completed much of the work that could plausibly require substantial input from agency counsel during the last administration, when they prepared and filed a full brief on the merits in an appeal to the Second Circuit, briefed a motion for summary judgment in a case pending in the Southern District of New York, and briefed several motions to dismiss and motions for preliminary relief.⁶ Defendants have also already compiled and produced the administrative record for the 2020 rule in the Southern District of New York. *See* Notice of Administrative Record, *New York v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-5583 (S.D.N.Y. Nov. 6, 2020), ECF No. 103 (notice confirming production of the administrative record to the plaintiffs and providing an index of its contents).

In any event, as this Court has noted, "being required to defend a suit, without more, does not constitute a clear case of hardship or inequity." *Ctr. for Biological Diversity v. Ross*, 419 F.

⁶ *See, e.g., Asapansa-Johnson Walker v. Azar*, Nos. 20-3580, 20-3827 (2d Cir.): Br. for Appellants (Doc. #3016175, filed Jan. 19, 2021); No. 1:20-cv-2834 (E.D.N.Y.): Opp. to Mot. for Prelim. Inj. (ECF No. 18, filed July 31, 2020); *New York v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-5583 (S.D.N.Y.): Mot. to Dismiss & Mem. in Support (ECF No. 112 & 113, filed Dec. 2, 2020); Opp. to Mot. for Summ. Judgment (ECF No. 130, filed Jan. 8, 2021); Reply in Support of Mot. to Dismiss (ECF No. 136, filed Jan. 20, 2021); *Whitman-Walker Health v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-1630 (D.D.C.): Opp. to Mot. for Prelim. Inj. (ECF No. 42, filed July 24, 2020); Surreply (ECF No. 48, filed Aug. 10, 2020); Mot. to Dismiss (ECF No. 57, filed Sept. 29, 2020); Reply in Support of Mot. to Dismiss (ECF No. 69, filed Jan. 19, 2021); *Boston Alliance of Gay, Lesbian, Bisexual, and Transgender Youth v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-11297 (D. Mass.): Mot. to Dismiss & Mem. in Support (ECF No. 21 & 22, filed Oct. 14, 2020); Reply in Support of Mot. to Dismiss (ECF No. 33, filed Dec. 9, 2020); *Washington v. U.S. Dep't of Health & Human Servs.*, No. 2:20-cv-1105 (W.D. Wash.): Opp. to Mot. for Prelim. Inj. (ECF No. 56, filed Aug. 10, 2020).

Supp. 3d 16, 21 (D.D.C. 2019) (cleaned up). The “burden of litigation is wholly insufficient to warrant a stay.” *Asylumworks v. Mayorkas*, No. 20-cv-3815-BAH, 2021 WL 2227335, at *6 (D.D.C. June 1, 2021).

Defendants’ only argument beyond the purported burden of litigating is that it could prove disruptive to regulated entities if the Court were to vacate provisions of the 2020 Revised Rule and the agency thereafter issues a new rule. These abstract concerns about future contingencies fail to carry the day—especially because the alternative is leaving a rule in effect as to which Plaintiffs and Defendants alike have “substantial and legitimate concerns” (Opp. at 1), with no fixed timeline for regulatory relief.

CONCLUSION

For the reasons stated above and in the Plaintiffs’ motion, Plaintiffs respectfully request that the Court lift the stay of proceedings in this case and deny Defendants’ request to hold this case in abeyance pending HHS’s reconsideration of the challenged 2020 Rule.

Dated this 20th day of August, 2021.

Respectfully submitted,

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* Admitted *pro hac vice*.

** Admitted *pro hac vice*. DC Bar admission
pending.

*** Application for admission to U.S. District
Court for the District of Columbia
forthcoming.

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Attorneys for Plaintiffs

Exhibit 1

From: [Omar Gonzalez-Pagan](#)
To: [Dos Santos, Joshua Y. \(CIV\)](#); [Holland, Liam C. \(CIV\)](#)
Cc: [Edelstein, Laurie](#); [Dennehy, Johanna](#); [Karen Loewy](#); [Cheung, Ashley \(CIV\)](#); [Scarborough, Charles \(CIV\)](#)
Subject: RE: WWH v. HHS (Case No. 1:20-cv-01630-JEB and Appeal No. 20-5331) - Request for meet and confer
Date: Wednesday, February 10, 2021 11:25:48 PM

Liam, Josh, and Ashley,

Thank you for taking the time to speak with us earlier today regarding how DOJ would like to proceed in this case. As discussed, we do not oppose moving to stay the proceedings in the district court and the court of appeals thru May 14, 2021 in light of the EOs noted below. In addition, we discussed that any such motion/stipulation include language noting that the PI remains in place. We propose language similar to the following, which has been included in the stipulations in *Immigration Equality v. DHS*, No. 20-cv-09258-JD (N.D. Cal.), and *Santa Cruz Gay and Lesbian Community Center v. Trump*, No. 20-cv-07741-BLF (N.D. Cal.):

“The preliminary injunction in this case enjoining the repeal of the definition of discrimination ‘[o]n the basis of sex’ insofar as it includes ‘discrimination on the basis of . . . sex stereotyping,’ as previously set forth in 45 C.F.R. § 92.4, and the incorporation of the religious exemption contained in Title IX, see 45 C.F.R. § 92.6(b), contained in the 2020 Revised Rule will remain in effect and Defendants will continue to adhere to this Court’s order enjoining implementation, enforcement, or application of these aspects of the Revised Rule.”

Finally, we discussed, at minimum, filing the motion/stipulation for a stay before the DC Circuit ahead of the status conference set for February 17th. Thank you for the time. We look forward to reviewing and signing off on a proposed filing.

Omar

Omar Gonzalez-Pagan

[Pronouns](#): He/Him/His

Lambda Legal

Lambda Legal: Making the case for equality

From: Omar Gonzalez-Pagan

Sent: Tuesday, February 9, 2021 1:08 PM

To: Dos Santos, Joshua Y. (CIV) <Joshua.Y.Dos.Santos@usdoj.gov>; Holland, Liam C. (CIV) <Liam.C.Holland@usdoj.gov>

Cc: Edelstein, Laurie <ledelstein@Steptoe.com>; Dennehy, Johanna <jdennehy@Steptoe.com>; Karen Loewy <KLoewy@lambdalegal.org>; Cheung, Ashley (CIV) <Ashley.Cheung@usdoj.gov>; Scarborough, Charles (CIV) <Charles.Scarborough@usdoj.gov>

Subject: RE: WWH v. HHS (Case No. 1:20-cv-01630-JEB and Appeal No. 20-5331) - Request for meet and confer

Absolutely. No problem.

Omar Gonzalez-Pagan

[Pronouns](#): He/Him/His

Lambda Legal

Lambda Legal: Making the case for equality

From: Dos Santos, Joshua Y. (CIV) <Joshua.Y.Dos.Santos@usdoj.gov>

Sent: Tuesday, February 9, 2021 1:07 PM

To: Omar Gonzalez-Pagan <ogonzalez-pagan@lambdalegal.org>; Holland, Liam C. (CIV) <Liam.C.Holland@usdoj.gov>

Cc: Edelstein, Laurie <ledelstein@steptoe.com>; Dennehy, Johanna <jdennehy@steptoe.com>; Karen Loewy <KLoewy@lambdalegal.org>; Cheung, Ashley (CIV) <Ashley.Cheung@usdoj.gov>; Scarborough, Charles (CIV) <Charles.Scarborough@usdoj.gov>

Subject: RE: WWH v. HHS (Case No. 1:20-cv-01630-JEB and Appeal No. 20-5331) - Request for meet and confer

Hi Omar,

Thanks for sending the invite. Can you add my colleagues Ashley Cheung and Charlie Scarborough, copied here?

Thanks very much,

Josh

Josh Dos Santos

Civil Appellate

U.S. Department of Justice

(202) 353-0213

From: Omar Gonzalez-Pagan <ogonzalez-pagan@lambdalegal.org>

Sent: Tuesday, February 9, 2021 12:21 PM

To: Holland, Liam C. (CIV) <Liam.C.Holland@usdoj.gov>; Dos Santos, Joshua Y. (CIV) <Joshua.Y.Dos.Santos@usdoj.gov>

Cc: Edelstein, Laurie <ledelstein@steptoe.com>; Dennehy, Johanna <jdennehy@steptoe.com>; Karen Loewy <KLoewy@lambdalegal.org>

Subject: RE: WWH v. HHS (Case No. 1:20-cv-01630-JEB and Appeal No. 20-5331) - Request for meet and confer

Thanks, Liam. Let's plan to speak tomorrow at 3pm ET. I will circulate a calendar invite.

Omar Gonzalez-Pagan

Pronouns: He/Him/His

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From: Holland, Liam C. (CIV) <Liam.C.Holland@usdoj.gov>

Sent: Monday, February 8, 2021 6:50 PM

To: Omar Gonzalez-Pagan <ogonzalez-pagan@lambdalegal.org>; Dos Santos, Joshua Y. (CIV) <Joshua.Y.Dos.Santos@usdoj.gov>

Cc: Edelstein, Laurie <ledelstein@steptoe.com>; Dennehy, Johanna <jdennehy@steptoe.com>; Karen Loewy <KLoewy@lambdalegal.org>

Subject: RE: WWH v. HHS (Case No. 1:20-cv-01630-JEB and Appeal No. 20-5331) - Request for meet and confer

Good Evening Omar,

We are available for a joint call at the following times:

Tuesday, except 2-4.

Wednesday, except 12:30-1:30

Thursday, except 9:30-10:30 or 4-5pm.

Friday, except 1-3.

Please let us know when works best for you.

Sincerely,
Liam

From: Omar Gonzalez-Pagan <ogonzalez-pagan@lambdalegal.org>

Sent: Friday, February 5, 2021 1:42 PM

To: Holland, Liam C. (CIV) <Liam.C.Holland@usdoj.gov>; Dos Santos, Joshua Y. (CIV) <Joshua.Y.Dos.Santos@usdoj.gov>

Cc: Edelstein, Laurie <ledelstein@steptoe.com>; Dennehy, Johanna <jdennehy@steptoe.com>; Karen Loewy <KLoewy@lambdalegal.org>

Subject: WWH v. HHS (Case No. 1:20-cv-01630-JEB and Appeal No. 20-5331) - Request for meet and confer

Liam and Josh,

We writing to request a meet and confer in light of the district court's order setting a telephonic hearing on February 17, 2021 "to discuss whether the change in administrations will have any effect on either side's position in this litigation." See Minute Order, Feb. 1, 2021. Given the change in administrations as well as President Biden's "[Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation](#)" and "[Executive Order on Strengthening Medicaid and the Affordable Care Act](#)," both which require a review of the Revised Rule, we should discuss how to proceed with the litigation ahead of the status conference. In addition, we believe that in light of the executive orders, the appeal of the preliminary injunction in this case should be withdrawn and that we should avoid unnecessary briefing or expenditure of resources.

Please let us know if you are available to meet and confer next week or how you would like to proceed.

Regards,

Omar

Omar Gonzalez-Pagan

Senior Attorney*

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Exhibit 2

RIN Data

HHS/OCR

RIN: 0945-AA17

Publication ID: Spring 2021

Title: •Nondiscrimination in Health Programs and Activities

Abstract:

This proposed rulemaking would propose changes to the 2020 Final Rule implementing section 1557 of the Patient Protection and Affordable Care Act (PPACA), and conforming amendments to related HHS rules. Section 1557 of PPACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under title I of the PPACA.

Agency: Department of Health and Human Services(HHS)

Priority: Economically Significant

RIN Status: First time published in the Unified Agenda

Agenda Stage of Rulemaking: Proposed Rule Stage

Major: Undetermined

Unfunded Mandates: Undetermined

CFR Citation: [42 CFR 438](#) [42 CFR 440](#) [42 CFR 460](#) [45 CFR 86](#) [45 CFR 92](#) [45 CFR 147](#) [45 CFR 155 and 156](#) ... (To search for a specific CFR, visit the [Code of Federal Regulations](#).)

Legal Authority: [sec. 1557 of the Patient Protection and Affordable Care Act \(42 U.S.C. 18116\)](#) [Civil Rights Restoration Act \(Pub. L. 100259, 102 Stat. 28 \(Mar. 22 1988\)\)](#) [L. 100259, 102 Stat. 28 \(Mar. 22 1988\)](#) [42 U.S.C. 2000d et seq. \(title VI of the Civil Rights Act of 1964, as amended\)](#) [29 U.S.C. 794 \(sec. 504 of the Rehabilitation Act of 1973, as amended\)](#) [20 U.S.C. 1681 et seq. \(title IX of the Education Amendments of 1972, as amended\)](#) [42 U.S.C. 6101 et seq.](#) (Age Discrimination Act of 1975, as amended) [Lau v. Nichols, 414 U.S. 563 \(1974\)](#) [5 U.S.C. 301](#) [42 U.S.C. 300jj-11, 300jj-14, 1302, 1395i, 1395eee\(f\), and 1396u4\(f\)](#), 18021 to 18024 , 18031 to 18033 , 18041 to 18042 , 18044, 18051, 18054, 18061, 18063, 18071, and 18081 to 18083 [26 U.S.C. 36B](#) [31 U.S.C. 9701](#) ...

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2022	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Included in the Regulatory Plan: No

RIN Data Printed in the FR: No

Agency Contact:

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