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14 IN THE UNITED STATES DISTRICT COURT  
 15 FOR THE NORTHERN DISTRICT OF CALIFORNIA

17 CITY AND COUNTY OF SAN FRANCISCO, Plaintiff, 18 vs. 19 ALEX M. AZAR II, et al., Defendants.
20 STATE OF CALIFORNIA, by and through 21 ATTORNEY GENERAL XAVIER BECERRA, Plaintiff, 22 vs. 23 ALEX M. AZAR, et al., Defendants.
24 COUNTY OF SANTA CLARA, et al. 25 Plaintiffs, 26 vs. 27 U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., 28 Defendants.

No. C 19-02405 WHA  
 No. C 19-02769 WHA  
 No. C 19-02916 WHA

**PLAINTIFFS’ RESPONSE TO ORDER  
 RE USE OF TERM “ENTITY”**

Date: October 30, 2019  
 Time: 8:00 AM  
 Courtroom: 12  
 Judge: Hon. William H. Alsup  
 Action Filed: 5/2/2019

1 **I. THE 2019 RULE’S DEFINITION OF “ENTITY” INCLUDES “HEALTH CARE ENTITIES”**

2 The answer to the question posed in the Court’s November 8, 2019 Order is yes. Church  
3 does not use the term “health care entity,” only “entity.” The Rule, however, defines the term  
4 “entity” to include essentially anyone, including all health care entities. It defines “entity” as:

5 a ‘person’ as defined in 1 U.S.C. 1; the Department; a State, political subdivision of  
6 any State, instrumentality of any State or political subdivision thereof; any public  
7 agency, public institution, public organization, or other public entity in any State or  
8 political subdivision of any State; or, as applicable, a foreign government, foreign  
9 nongovernmental organization, or intergovernmental organization . . . .

8 84 Fed. Reg. 23,263 (Section 88.2). In turn, Section 1 of the U.S. Code defines “person” to  
9 “include corporations, companies, associations, firms, partnerships, societies, and joint stock  
10 companies, as well as individuals.” In other words, HHS’s “entity” definition includes—without  
11 limitation—any corporation, company, individual, government, or public agency.<sup>1</sup> The subset of  
12 corporations, companies, individuals, and public entities that also qualify as “health care entities”  
13 under the Rule *necessarily* fall within this capacious definition of “entity.”

14 The regulatory history of the terms “entity” and “health care entity” supports this  
15 conclusion. The 2019 Rule seeks to “generally reinstate” HHS’s 2008 rule.<sup>2</sup> 84 Fed. Reg. 23,179.  
16 In that earlier rule, HHS subsumed the term “entity” as used in Church under the definition of  
17 “health care entity” as used in Weldon and Coats-Snowe. *See* 73 Fed. Reg. 78,072, 78,076 (Dec.  
18 19, 2008) (“[T]he Department thought it would be beneficial to provide a clear and consistent  
19 definition that it would apply when implementing any of the three statutes.”); *id.* at 78,091  
20 (Church “does not define the term ‘entity,’ and does not use the term ‘health care entity.’ In  
21 keeping with the definitions in PHS Act § 245 and the Weldon Amendment, the Department  
22 proposed to define ‘health care entity’ to include the specifically mentioned types of individuals

23 \_\_\_\_\_  
24 <sup>1</sup> HHS has argued that although there is no limiting principle within the definition of “entity”  
25 itself, “[f]or some statutes . . . , the Applicability paragraph [of the Rule] by its own terms may  
26 only implicate certain types of entities or only entities receiving certain types of funding.” 84 Fed.  
27 Reg. 23,170. While the Applicability paragraph concerning the Church Amendment indicates that  
28 it applies only to entities that receive certain funding, nothing in that paragraph limits the types of  
29 entities covered. *Id.* at 23,264-65 (Section 88.3(a)(1)).

<sup>2</sup> The 2008 rule never meaningfully went into effect. *See New York v. U.S. Dep’t of Health &*  
*Human Servs.*, 2019 WL 5781789, at \*8–\*9 (S.D.N.Y. Nov. 6, 2019). It became effective on  
January 20, 2009 without the certification requirements and was rescinded by the 2011 rule on  
February 23, 2011. During that period, it appears it was not enforced. *Id.* at \*8.

1 and organizations from the two statutes, as well as other types of entities referenced in the Church  
 2 Amendments.”). While the 2008 rule used identical definitions for the terms “entity” and “health  
 3 care entity,” *id.* at 78,097, the 2019 Rule is even broader, going beyond the definitions covered by  
 4 the 2008 Rule. 84 Fed. Reg. 23,179, 23,263.<sup>3</sup>

5 Defendants may argue that the 2019 Rule attempts to limit “health care entity”—contending  
 6 that it applies only to instances specific to Weldon, Coats-Snowe, and ACA Section 1553. But the  
 7 2019 Rule makes clear that “health care entity” applies broadly to *any* circumstance in which a  
 8 conscience objection may be made. *Id.* at 23,184 (“If the Department becomes aware that a State  
 9 or local government or a health care entity may have undertaken activities that may violate *any*  
 10 statutory conscience protection...” (emphasis added); 23,194–96 (“health care entity”  
 11 encompasses a non-exclusive list that may vary case-by-case).<sup>4</sup> This renders unavailing any  
 12 argument by HHS that the 2019 Rule applies the term “health care entity” only to statutes that  
 13 include that term—namely, Weldon, Coats-Snowe, and ACA Section 1553.

## 14 **II. HHS’S DEFINITION OF “ENTITY” CONFLICTS WITH CHURCH**

15 HHS’s definition of the term “entity” conflicts with Church. As an initial matter, the  
 16 language, context, and legislative history of Church establish that it was intended to apply to  
 17 those with a close nexus to the procedure, like doctors and nurses, as well as religious hospitals.  
 18 By defining entity broadly enough to sweep in countless others, HHS has contravened Congress’s  
 19 will. Moreover, both Coats-Snowe and Weldon define “health care entity” to include both  
 20 individuals and certain institutions. *See* 42 U.S.C. § 238n(c)(2); 132 Stat. 2981, 3118. But Church  
 21 carefully distinguishes between an “entity” and an “individual,” with some provisions applying to  
 22 entities, some applying to individuals, and some applying to both. *See, e.g.*, 42 U.S.C. § 300a-  
 23 7(b) (“The receipt of any grant, contract, loan, or loan guarantee under [the covered Acts] by any

24 \_\_\_\_\_  
 25 <sup>3</sup> In 2011, HHS rescinded the 2008 definitions, stating that the 2008 Rule had “caused confusion  
 26 regarding the scope of the federal health care provider conscience protection statutes” and might  
 27 “negatively affect the ability of patients to access care if interpreted broadly.” 76 Fed. Reg. at  
 28 9973–74; *see also New York*, 2019 WL 5781789, at \*9. HHS’s failure even to acknowledge that  
 the 2011 rule rescinded the previous definition for fear of creating confusion is arbitrary and  
 capricious. *New York*, 2019 WL 5781789, at \*46.

<sup>4</sup> *See also* <https://www.hhs.gov/sites/default/files/final-conscience-rule-factsheet.pdf> (combining  
 conscience protections of various provisions as protecting “health care entities and employees”).

1 *individual or entity* does not authorize any court or any public official or other public authority to  
2 require -- (1) such *individual* to [take certain actions], or (2) such *entity* to [take certain actions]”);  
3 *id.* § 300a-7(c) (imposing requirements on “entit[ies]”); *id.* § 300a-7(d) (granting certain  
4 protections to an “individual”). It is clear from this language that the term “entity,” as used in  
5 Church, was intended to exclude individual persons. *See S.E.C. v. McCarthy*, 322 F.3d 650, 656  
6 (9th Cir. 2003) (“It is a well-established canon of statutory interpretation that the use of different  
7 words or terms within a statute demonstrates that Congress intended to convey a different  
8 meaning for those words.”). Therefore, the term “entity” as used in Church cannot encompass the  
9 term “health care entity” as used in either Coats-Snowe or Weldon, because the phrase as defined  
10 in those provisions includes specified categories of individuals.

### 11 **III. THE SUBSTANTIVE EXPANSION OF THE CHALLENGED DEFINITIONS REQUIRES** 12 **VACATUR**

13 The Rule’s expansion of the definition of “entity” is but one of numerous ways that the  
14 Rule exceeds the scope of HHS’s authority, making vacatur the appropriate remedy. *New York* ,  
15 2019 WL 5781789, at \*24, \*29, \*66 (vacating the Rule because, *inter alia*, HHS lacked authority  
16 to substantively alter statutory definitions). Indeed, this Court need look no further than the  
17 definitions of the terms “assist in the performance,” “refer,” “healthcare entity,” and  
18 “discrimination” to vacate the Rule, as those definitions go to the heart of the Rule and create a  
19 new system for refusals and accommodation. Congress did not grant HHS the authority to  
20 construe Church to cover such a broad range of funding recipients—imposing substantive  
21 obligations and creating refusal rights and enforcement powers never contemplated in the statute.  
22 *New York*, 2019 WL 5781789, at \*29, \*33, \*66-67 (“With respect to the Church, Coats-Snowe,  
23 and Weldon Amendments, HHS was never delegated and did not have substantive rule-making  
24 authority”); Pls.’ Mot. 27-30; Pls.’ Reply 3-7. Based on these and several other independent  
25 violations of the APA demonstrated by Plaintiffs, as well as the Rule’s constitutional infirmities,  
26 vacatur of the Rule is warranted. *New York*, 2019 WL 5781789, at \*67-72 (citations omitted);  
27 Pls.’ Mot. 30-35, 54-55; Pls.’ Reply 3-7, 20.

1 Respectfully Submitted,

2 Dated: November 12, 2019

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**CERTIFICATE OF SERVICE**

I hereby certify that the foregoing was electronically filed with the Clerk of the Court for the United States District Court for the Northern District of California by using the ECF system on November 12, 2019. All participants in the case who are registered ECF users will be served by the ECF system.

By: /s/ Lee H. Rubin