No. 19–15074

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

John Doe One, John Doe Two, John Doe Three, John Doe Four and John Doe Five, on behalf of themselves and all others similarly situated,

Plaintiffs/Appellants, v.

CVS Pharmacy, Inc.; Caremark L.L.C.; Caremark California Specialty Pharmacy, L.L.C.; National Railroad Passenger Corporation d/b/a Amtrak; Lowe's Companies, Inc.; and Time Warner Inc.

Defendants/Appellees.

PLAINTIFFS/APPELLANTS' OPENING BRIEF

On Appeal From The United States District Court
For The Northern District of California
Case No. 3:18–cv–01031–EMC

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INTRODUCTION

The claims asserted in the First Amended Complaint ("Complaint") by Plaintiffs John Does One through Five ("Appellants")[1] under the Affordable Care Act ("ACA"), Americans with Disabilities Act ("ADA"), Employee Retirement Income Security Act ("ERISA"), California's Unruh Civil Rights Act ("Unruh Act") and Unfair Competition Law ("UCL"), all arise out of Appellees' discriminatory business practices against patient-enrollees who are prescribed medications for the treatment or prevention of HIV and AIDS ("HIV/AIDS Medications"). The mandatory prescription drug mail-order program at issue in this action (the "Program") constitutes unlawful discrimination because it denies Appellants and putative class members "meaningful access" to their prescription drug benefits. *See Alexander v. Choate*, 469 U.S. 287, 301 (1985) ("[A]n otherwise qualified handicapped individual must be provided with meaningful access to the benefit the grantee offers.").

Appellants are members of a group who have historically faced discrimination throughout the healthcare system. Before Congress passed the ACA, the business model of health insurance incentivized insurers and pharmacy benefit managers ("PBMs") to avoid covering individuals like Appellants who have significant

[1] Appellants have filed a motion to correct a clerical error in the caption to refer to John Does One through Five instead of One through Four.

healthcare needs. Moreover, before the ACA, these entities were allowed to engage in discriminatory benefit design practices–similar to those at issue here–that were not prohibited under anti-discrimination laws at the time. *See, e.g.*, *Doe v. Mut. of Omaha Ins. Co.*, 179 F.3d 557, 588 (7th Cir. 1999) (lifetime caps on coverage for AIDS did not discriminate based on disability). Though the law has changed, some PBMs' practices have not.

The ACA purposefully and explicitly created a new standard to eliminate discriminatory limits on access to healthcare. As people living with HIV/AIDS "have suffered disproportionately from lack of healthcare access, Congress included a number of consumer protections [in the ACA] prohibiting health insurance providers from denying [HIV/AIDS patients] coverage."[2] A central premise of the ACA embodied in both its prohibitions against denying coverage due to a pre–existing condition (42 U.S.C. §§ 300gg-1, 300gg–2) and provisions barring discrimination on the basis of disability (42 U.S.C. §§ 300gg–4, 18116; 45 C.F.R. §§ 92.207(a)–(b)) is to ban companies from imposing discriminatory coverage that undermines meaningful access to care. The need for the latter prohibition is clear. Requiring companies to provide coverage for people living with HIV/AIDS means

[2] Mark Bolin, *The Affordable Care Act and People Living with HIV/AIDS: A Roadmap to Better Health Outcomes*, 23 Annals Health L. 28, 31 (2014) (http://www.annalsofhealthlaw.com/annalsofhealthlaw/vol_23_issue_1?pg=36#pg36).

little if the insurer or PBM is permitted to do so in a manner that puts Appellants' health and privacy at risk, denies them meaningful access to their prescription drug benefit, and discourages them from remaining enrolled in their healthcare plan.

Moreover, the ACA mandates comprehensive coverage in the form of ten broad Essential Health Benefits ("EHBs"). 42 U.S.C. § 18022(b)(1). The EHBs include the provision of prescription drugs, preventive and wellness services, and chronic disease management. *Id*.; 45 C.F.R. §§ 156.110(a)(6), (9) (relevant excerpts attached as Addendum A). Particularly relevant here, 45 C.F.R. § 156.122(e) (relevant excerpts attached as Addendum B) specifically defines what constitutes "meaningful access" to prescription drug benefits, providing that Appellants must be able to obtain their medications at all in–network pharmacies.[3] As noted by the U.S. Department of Health and Human Services ("HHS"), "[w]e … believe that making drugs available only by mail-order could discourage enrollment by, and thus discriminate against … individuals who have conditions that they wish to keep confidential. We also believe that this provision is important to ensure uniformity in benefit design and consumer choice." 80 Fed. Reg. 39, 10820–22 (Feb. 27, 2015) (relevant excerpts attached as Addendum C) .

[3] Though 45 C.F.R. § 156.122(e) may not directly regulate all healthcare plans at issue in this action, it does provide this Court an important benchmark for defining "meaningful access" to pharmacies and prescription drugs.

In addition to their well–pled allegations of violations of these ACA protections, as set forth below Appellants also sufficiently alleged *prima facie* ADA and Unruh Act claims. The central issue under the ADA claim, and relatedly under the Unruh Act, is whether CVS Caremark[4] can legitimately deny individuals prescribed HIV/AIDS Medications access to network pharmacies, which have been found to be "places of public accommodation."

Appellants further alleged that the implementation of the Program foreclosing their access to HIV/AIDS Medications through network pharmacies worked an unlawful reduction in the benefits due under their plans, giving rise to a claim for benefits due under, *inter alia*, Section 502(a)(1)(B) of ERISA. The district court improperly dismissed the ERISA claim on the grounds Appellants had not alleged a specific plan term entitling them to access their medications through independent pharmacies, stating that while "Plaintiffs 'had *previously* been able to obtain' medications from community pharmacies … [t]hey do not allege that under the Program, they are *still* entitled to the same benefit." Excerpt of the Record ("EOR") 213. The district court also improperly dismissed the UCL claim for not properly alleging additional "unlawful" practices beyond the above federal claims and for failure to properly allege "unfair" practices, even though the Complaint alleged

[4] For purposes of this brief, "CVS Caremark" refers collectively to Defendants CVS Pharmacy, Inc.; Caremark, L.L.C.; and Caremark California Specialty Pharmacy, L.L.C.

additional violations of laws and detailed why such conduct violated public policy and created significant harms. EOR 180.

JURISDICTIONAL STATEMENT

The district court has jurisdiction over Appellants' federal claims under 28 U.S.C. §§ 1331 and 1332(d). The district court has supplemental jurisdiction over the state–law claims under 28 U.S.C. § 1367.

The district court entered its Judgment and Order Granting Defendants' Motions to Dismiss dismissing all of the claims asserted in the Complaint with prejudice on December 12, 2018. Appellants filed a timely notice of appeal on January 11, 2019. EOR 219–224. This Court has jurisdiction over the appeal pursuant to 28 U.S.C. § 1291.

STATEMENT OF ISSUES PRESENTED FOR REVIEW

(1) Whether Appellants adequately pled a claim of disability discrimination under the ACA when they alleged that the design and administration of the Program denied them meaningful access to their prescription drug benefits solely on the basis of their disability.

(2) Whether Appellants adequately pled a claim of disability discrimination under Section 504 of the Rehabilitation Act, 29 U.S.C. § 794 *et seq*. ("Section 504"), which is incorporated into the ACA under Section 1557 of the ACA ("Section 1557"), as well as the Unruh Act, based on their allegations that

administration of the Program denied them reasonable accommodations necessary to utilize their healthcare benefits.

(3) Whether Appellants adequately pled a claim of disability discrimination under the ADA and the Unruh Act based on their allegations CVS Caremark denied thousands of enrollees access to "places of public accommodation," *i.e.*, the network pharmacies.

(4) Whether Appellants adequately pled claims for denial of benefits under ERISA based on how the Program was implemented.

(5) Whether Appellants adequately pled claims based on violations of the independent "unlawful" and "unfair" prongs of the UCL.

STATEMENT OF THE CASE

A. The Program at Issue

CVS Caremark has established a national network of pharmacies where consumers may obtain their medications under the terms of their healthcare plans. In its role as PBM, CVS Caremark boasts that enrollees have access to a "national network of more than 68,000 retail pharmacies," including many independent community pharmacies,[5] almost 10,000 CVS–branded stores, and other major

[5] CVS Caremark, *Our Programs: Pharmacy Networks*, https://www.cvshealth.com/about/our-offerings/cvs-caremark (last visited June 4, 2019).

chains (collectively, the "Network Pharmacies").[6] However, under the Program, CVS Caremark established a separate and unequal pharmacy network administered by a CVS Health Corporation subsidiary to be used virtually exclusively for individuals who need medications to treat their disabilities, including those with HIV/AIDS. EOR 38, 48, ¶¶ 70, 94 n.8. HIV/AIDS enrollees in health plans where CVS Caremark controls and administers the pharmacy benefits are told they can only obtain their HIV/AIDS Medications by mail-order or drop-shipment to a CVS–branded store. However, where "CVS Caremark mails the medications to a CVS Pharmacy, but only as a drop shipment location purely for pickup, [there is] *no advice provided by a pharmacist*." EOR 23, ¶ 25. (emphasis added). Therefore, as a result of the Program, Appellants have lost access to 85% of Network Pharmacies, and 100% of pharmacists.

B. HIV Patients Lose Meaningful Access to Prescription Drug Benefits

At issue in this action are three prescription drug benefits—the medication itself, access to Network Pharmacies, and access to pharmacists. Appellants and

[6] CVSHealth, *Network Strategies*, https://payorsolutions.cvshealth.com/programs-and-services/cost-management/network-strategies?utm_source=CVSHealth.com&utm_medium=Website%20Link&utm_campaign=Corporate%20Site%20Link%20Referral&utm_content=Link%20to%20Network%20Strategies%20Page (last visited June 4, 2019).

putative Class members are subject to unlawful discrimination in accessing these benefits.

1. HIV/AIDS Medications

HIV is a particularly difficult condition to treat because without proper treatment the virus continually mutates around medications prescribed to treat it. EOR 46, ¶ 89. The mail-order delivery of HIV/AIDS Medications can lead to drug dosage interruptions for HIV/AIDS patients for whom strict adherence is necessary to prevent serious health problems. EOR 32–34, 36–37, 42, 46, 84, ¶¶ 51, 55, 62, 66, 77, 90, 147. The mail-order delivery of HIV/AIDS Medications may also lead to the reduced efficacy of HIV/AIDS Medications if they are exposed to heat or sunlight during the delivery process. EOR 23, ¶ 24. Additionally, the Program's delivery of HIV/AIDS Medications results in serious privacy concerns for HIV/AIDS patients forced to receive deliveries at their workplace or home, as many have not disclosed their HIV/AIDS status to colleagues, roommates, or family. EOR 40–41, ¶ 74. Similar privacy concerns arise at CVS-branded stores. EOR 26, 42, ¶¶ 33, 76. The improper disclosure of a person's HIV/AIDS status can result in numerous collateral consequences including denial of proper healthcare and adverse treatment in educational and work settings. EOR 40–41, ¶ 74.

2. Network Pharmacies

Access to the full CVS pharmacy network is an essential benefit of Appellants' health plans. However, the Program has been designed and administered in a manner that has placed Appellants into a separate and unequal pharmacy network resulting in a loss of access to 85% of Network Pharmacies. Despite the promises of CVS Caremark regarding the benefits of the Program, it fails to provide similar quality of care compared to Network Pharmacies that Appellants previously had access to, and that other enrollees still have access to for other medications. EOR 24–28, 30–33, 35–36, ¶¶ 29–30, 33, 38–39, 46, 51, 60–62.

3. Access to Pharmacists

The importance of the relationship between a community pharmacist and people living with HIV/AIDS cannot be overstated, as the pharmacy is the center point of their healthcare treatment. EOR 43–45, ¶¶ 80, 83–86. Consultations with knowledgeable pharmacists are critical to monitor and address complicated, everchanging drug regimens, potentially dangerous drug interactions, and side effects associated with medications needed to treat their condition. Expert oversight of medications is essential to address the complex nature of HIV/AIDS and to remedy substantial side effects that could result from interactions among the multiple drugs that HIV/AIDS patients often take concurrently. EOR 24–25, 27, 31, 33, 36–39, 44–46, ¶¶ 29, 38, 47, 54, 64, 70, 81–84, 86, 88–89.

However, under the Program, HIV/AIDS patients are not provided access to a pharmacist with necessary qualification levels, if at all. EOR 46–47, 71 ¶¶ 91, 95. While CVS Caremark touts access to CVS-branded pharmacies nationwide, these are merely drop-shipment locales, little more than P.O. Boxes or Amazon lockers. Because the pharmacy is just a pickup location, enrollees have no access to pharmacists–let alone ones specializing in HIV/AIDS Medications. EOR 41–42, 84–85, ¶¶ 75, 147. The mail-order Program representatives Appellants have spoken with over the phone are poorly trained and have no specialized knowledge about HIV/AIDS Medications, the concerns of HIV patients, or even Appellants' medical histories. EOR 27–28, 30–32, 35, 37, 45–47, ¶¶ 39, 46, 48, 60, 65, 85, 91.

Appellants have repeatedly attempted to resolve their problems with the Program before bringing this action, to no avail. EOR 23, 28–30, 33–36, ¶¶ 22–23, 40–41, 45, 55, 60–61. This is likely because companies like CVS Caremark make more profits when they deliver drugs through mail-order than through a retail network system.[7] EOR 43, 79–80, ¶¶ 79, 128. Appellants simply seek access to the same Network Pharmacies that other enrollees have access to.

[7] Specialty pharmacy programs are good for profits, but not patients. PBMs "earn a higher profit when they go to a specialty pharmacy. … But if you need that drug on a Saturday or Sunday, you're probably not going to get it." Olga Khazan, *Invisible Middlemen Are Slowing Down American Health Care*, The Atlantic (Apr. 9, 2019), https://www.theatlantic.com/health/archive/2019/04/pbms-health-care-drug-delays-prices/586711/.

SUMMARY OF ARGUMENT

The district court erred in dismissing all claims asserted in the Complaint for numerous reasons:

First, the district court erred in finding that Appellants failed to adequately plead a violation of the discrimination standard adopted under Section 1557 by alleging that (1) they are qualified individuals with a disability due to their HIV/AIDS status; (2) CVS Caremark is a "health program or activity," part of which receives federal financial assistance; and, (3) CVS Caremark "excluded [them] from participation in, … denied [them] the benefits of, or … subjected [them] to discrimination under" the benefits of their prescription drug plan on the basis of their disability. EOR 185.

Second, the district court erred in holding Appellants failed to allege a disparate impact claim under Section 504 because the Program applies to medications that treat disabilities as well as those that do not. This portion of the district court's order misapplied the meaningful access standard that courts employ to show disability discrimination. EOR 188–190. A facially neutral policy that applies to both disabled and nondisabled individuals yet results in a disproportionate harm due to a disability is an essential element of a discrimination claim based on a disparate impact theory. *See Crowder v. Kitagawa*, 81 F.3d 1480, 1484 (9th Cir. 1996) (quarantine requirement that "applie[d] equally to all persons" burdened

visually impaired persons "in a manner different and greater than it burdens others" and effectively denied meaningful access to state services held to discriminate against plaintiffs by reason of their disability).[8]

Third, the district court erred by failing to consider whether the Program's design violates Section 1557. Appellants alleged that "[p]articipation in the [P]rogram threatens [Appellants'] health and privacy;" EOR 83, ¶ 145; "violat[es] … the standards of good healthcare and clinically appropriate care for HIV/AIDS patients;" EOR 42, ¶ 78; and "[d]enies [them] the full benefit of their healthcare plans' drug benefit" because of their disability. EOR 84, ¶ 147. Though CVS Caremark may technically "supply" Appellants' HIV/AIDS Medications under the Program, providing HIV/AIDS Medications in a manner that sabotages their treatment is not "meaningful access" under *Alexander*, 469 U.S. at 301, or any reasonable interpretation of the meaningful access standard since the adoption of the ACA. In fact, federal regulations implementing the ACA define meaningful access to prescription drugs: "A health plan must allow enrollees to access prescription drug benefits at in–network retail pharmacies, unless …" the drug is subject to certain conditions. 45 C.F.R. § 156.122(e). The Complaint alleges the exceptions listed in

[8] This Court "examine[s] cases construing claims under the ADA, as well as section 504 of the Rehabilitation Act, because there is no significant difference in the analysis of rights and obligations created by the two Acts." *Vinson v. Thomas*, 288 F.3d 1145, 1152 n.7 (9th Cir. 2002).

45 C.F.R. § 156.122(e)(1)(i)–(ii) are not applicable to Appellants' HIV/AIDS Medications. EOR 77–78, ¶ 123–24.

Fourth, the district court erred when it concluded that the discriminatory effects alleged by Appellants are merely "inconvenience[s]" that insureds with HIV/AIDS endure "as a result of Defendant's policy," and, therefore, are not so significant as to constitute a denial of meaningful access to Plaintiffs' prescription drug benefits. EOR 192–193. As the Program harms insureds with HIV/AIDS uniquely and disproportionately in that the Program inadequately accounts for their specific needs such that it effectively reduces access to their prescription drug benefits, Appellants properly allege discrimination takes place. Under the district court's analysis, a court would be required to conclude that if an individual with a disability receives any benefit *at all*, the access is "meaningful." Both Supreme Court and Ninth Circuit jurisprudence applying the meaningful access standard do not recognize such an absolutist approach.

Fifth, the district court erred when it ignored specific factual allegations of CVS Caremark's denial of Appellants' reasonable accommodation requests when it wrongly concluded Appellants' allegations are insufficient to allege an intentional discrimination claim under Section 1557, the ADA, and the Unruh Act. EOR 187 at n.4, 196–198.

Sixth, the district court erred in ruling that Appellants seek a fundamental change to the benefit program such that Appellants' requested reasonable accommodation need not be granted. EOR 191–192. "Fundamental change" is an affirmative defense inappropriate on a motion to dismiss; such a defense requires a fact–specific inquiry by the district court. *Townsend v. Quasim*, 328 F.3d 511, 520 (9th Cir. 2003) (remanding for further proceedings to determine whether the defendant "can demonstrate that the modifications requested by the plaintiff class 'would fundamentally alter the nature of the services'" provided.).

Seventh, the district court erred when it concluded as a matter of law based on its misreading of *Weyer v. Twentieth Century Fox Film Corp.*, 198 F.3d 1104 (9th Cir. 2000), that the "health plan" was the "place of public accommodation" that was the subject of Appellants' ADA claim rather than the Network Pharmacies controlled by CVS Caremark. Contrary to the district court's ruling, Appellants alleged that the places of public accommodation they are denied access to are the Network Pharmacies that are now "out of network" for Appellants' HIV/AIDS Medications as a result of the Program, while other enrollees may access the same Network Pharmacies for other medications.

Eighth, because there was no allegation or evidence that the employer plans in question were validly amended, the district court erred when it dismissed Appellants' ERISA claim on the grounds that "Plaintiffs 'had *previously* been able

to obtain' medications from community pharmacies … [t]hey do not allege that under the Program, they are *still* entitled to the same benefit." EOR 213. This holding incorrectly conflated the mail-order Program with the ERISA plan itself, contrary to the allegations of the Complaint.

Ninth, because Appellants properly alleged claims under the above laws, the district court erred in dismissing their claims under the "unlawful" prong of the UCL. The district court also erred in finding Appellants had not alleged predicate violations of the California Constitution's right of privacy, as well as finding inadequate the allegations of an "unfair" business practice.

STANDARD OF REVIEW

This court reviews *de novo* a district court's dismissal for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). *Aguayo v. U.S. Bank*, 653 F.3d 912, 917 (9th Cir. 2011). "Questions of statutory interpretation are reviewed de novo. ..." *Lopez v. Wash. Mut. Bank*, 302 F.3d 900, 903 (9th Cir. 2002) (citations omitted). "[F]or a complaint to survive a motion to dismiss, the non–conclusory 'factual content' and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief." *Moss v. U.S. Secret Srvc.*, 572 F.3d 962, 989 (9th Cir. 2009) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009)). Accordingly, "[a] complaint may be dismissed for failure to state a claim only when it fails to state a cognizable legal theory or fails to allege sufficient factual

support for its legal theories." *Caltex Plastics, Inc. v. Lockheed Martin Corp.*, 824 F.3d 1156, 1159 (9th Cir. 2016) (internal citation omitted).

ARGUMENT

I. The ACA Provides New Anti-Discrimination Standards to Ensure Comprehensive Coverage Without Discrimination

The district court erred when it concluded that a denial of meaningful access to enrollees' HIV/AIDS Medications, and a denial of access to 85% of Network Pharmacies and 100% of pharmacists essential to care for enrollees' health condition, can never be a form of disability discrimination if some insureds, no matter how few, who are not disabled are also subject to the Program. EOR 188–190. This decision is at odds with the plain language of the ACA, its implementing regulations, the guidance provided by HHS, other district court decisions interpreting Section 1557 of the ACA, Section 504 of the Rehabilitation Act and its implementing regulations, and traditional anti–discrimination principles applied by this Court. If upheld, the district court's decision would allow ACA–regulated health insurers and PBMs to revive outlawed pre-existing-condition limitations in a new form. Insurers and PBMs could exclude all treatment for HIV/AIDS, or other disabling conditions at will and without medical justification by adding a few nondisabled enrollees or a handful of medications that treat nondisabling health conditions to a program and point to that as evidence of nondiscriminatory treatment. That, of course, is the exact kind of discriminatory benefit design that Section 1557

outlawed. If the district court's ruling is not reversed, the ACA's key reforms, designed to protect insureds with disabilities and chronic health conditions, would be eviscerated.

As the district court noted, "[n]o consensus has yet emerged as to the standard for assessing ACA antidiscrimination claims." EOR 186. However, this Court must consider the ACA as a whole when interpreting Section 1557. "A fair reading of legislation demands a fair understanding of the legislative plan." *King v. Burwell*, 135 S. Ct. 2480, 2496 (2015); *see also id.* at 2493 ("We cannot interpret federal statutes to negate their own stated purposes."). Congressional intent must be gleaned in light of the remedial nature of the ACA, since comprehensive remedial statutes like the ACA are generally accorded "a sweep as broad as their language." *Griffin v. Breckenridge*, 403 U.S. 88, 97 (1971).

"In the [ACA], Congress addressed the problem of those who cannot obtain insurance coverage because of pre–existing conditions or other health issues." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 547 (2012). With its promises of guaranteed health coverage and protection for individuals with preexisting conditions, it is clear that Congress intended to change the landscape of health coverage in the United States by providing meaningful access to healthcare, and to do so by creating a "new, health-specific, antidiscrimination cause of action that is subject to a singular standard, regardless of a plaintiff's protected class status."

Rumble v. Fairview Health Services, No. 14cv2037, 2015 WL 1197415, at *11 (D. Minn. Mar. 16, 2015). Moreover, the protections under Section 1557 were specifically intended to protect those with HIV/AIDS. According to the federal Center for Disease Control and Prevention ("CDC"), the ACA "is one of the most important pieces of legislation in the fight against HIV/AIDS in our history."[9] The ACA recognized that "[h]istorically, people living with [HIV/AIDS] have had a difficult time obtaining private health insurance and have been particularly vulnerable to insurance industry abuses."[10] *See also* 155 CONG. REC. S12153-02 (Dec. 2, 2009) (relevant excerpts attached as Addendum D) (Senator Ben Cardin: the ACA "will help achieve the goals outlined by the theme of this year's World AIDS Day campaign of 'universal access and human rights.' First and foremost, the bill eliminates discrimination based on preexisting conditions. Individuals with HIV will no longer be rejected from insurance coverage because of their disease."); 156 CONG. REC. H1854–02 (March 21, 2010) (relevant excerpts attached as Addendum E) (Congressman Steny Hoyer, House Majority Leader: "It is more control ... [f]or consumers, and less for insurance companies. It is the end of discrimination against Americans with preexisting conditions, and the end of … caps on benefits."); Exec. Order Implementing the Nat'l HIV/AIDS Strategy for the United States for 2015–

[9] *The Affordable Care Act Helps People Living with HIV/AIDS*, https://www.cdc.gov/hiv/policies/aca.html (last visited June 4, 2019).
[10] *Id*.

2020, Exec. Order No. 13703, 80 Fed. Reg. 46181, 46182 (July 30, 2015) (relevant excerpts attached as Addendum F) ("In light of recent progress and continuing challenges, we must continue to improve our national effort to reduce new HIV infections, increase access to care for people living with HIV, reduce HIV-related disparities and health inequities…").

Therefore, the ACA generally, and Section 1557 in particular, expressly expanded and strengthened existing protections against discrimination for individuals with disabilities as the ACA was intended "to expand access to care and coverage and eliminate barriers to access." 81 Fed. Reg. 96, 31376–77 (May 18, 2016) (relevant excerpts attached as Addendum G). The ACA explicitly prohibits insurers and PBMs from employing health insurance benefit designs that discriminate on the basis of disability or otherwise discourage individuals with significant healthcare needs from enrolling in, or remaining enrolled in, healthcare plans. 45 C.F.R. §§ 156.122(e) (relevant excerpts attached as Addendum B); 156.110(d) (relevant excerpts attached as Addendum A); 156.125(a) (relevant excerpts attached as Addendum H). To this end, Section 1557 explicitly creates a new healthcare–specific anti–discrimination standard: An individual shall not on the "ground prohibited under title VI of the Civil Rights Act of 1964 [], title IX of the Education Amendments of 1972 [], the Age Discrimination Act of 1975 [], or section 504 of the Rehabilitation Act of 1973 [], be excluded from participation in, be denied

the benefits of, or be subjected to discrimination under, any health program or activity …" 42 U.S.C. § 18116 (internal citations omitted).

As the court in *Rumble v. Fairview Health Servs.* found, Congress "intended that the same standard and burden of proof apply to a Section 1557 plaintiff, regardless of [their] protected class status." 2015 WL 1197415, at *11–12. Reading Section 1557 otherwise "would lead to an illogical result, as different enforcement mechanisms and standards would apply to a Section 1557 plaintiff depending on whether [their] claim is based on her race, sex, age, or disability." *Id*; *but see Doe v. BlueCross BlueShield of Tenn., Inc.*, No. 18-5897, slip op. at 4 (6th Cir. June 4, 2019) (finding that the four enforcement mechanisms are separately incorporated). Courts must remain "cognizant of the fact that 'Section 1557 is unique among [f]ederal civil rights laws in that it specifically addresses discrimination in health programs and activities.'" *Callum v. CVS Health Corp.*, 137 F. Supp. 3d 817, 853 (D.S.C. 2015) (citing 80 Fed. Reg. 173, 54182) (relevant excerpts attached as Addendum I). In comments on regulations implementing Section 1557, HHS's Office for Civil Rights ("OCR") buttressed the *Rumble* court's reasoning:

> [G]iven that the Age Act authorizes a private right of action for disparate impact claims, a private right of action would exist for disparate impact claims for all forms of discrimination…. For example, it would not make sense for a … plaintiff claiming race discrimination to be barred from bringing a disparate impact [claim] but then allow a plaintiff alleging disability discrimination to do so… . *OCR interprets Section 1557 as authorizing a private right of*

> *action for claims of disparate impact discrimination on the basis of any of the criteria enumerated in the legislation*.

81 Fed. Reg. 96, 31439–40 (emphasis added). OCR's comment is consistent with the ACA's underlying purpose of eliminating barriers to access since many healthcare plan designs and benefits may be facially neutral but work to effectuate discrimination against people with disabilities.

Appellants adequately alleged disability discrimination under Section 1557:

(1) They alleged both they and others who must take HIV/AIDS Medications are qualified individuals with a disability due to their HIV/AIDS status. EOR 87, ¶ 156;

(2) They alleged that CVS Caremark is a "health program or activity," part of which receives federal financial assistance, that must comply with Section 1557. EOR 83, ¶ 143; 42 U.S.C. §18116(a); 45 C.F.R. § 92.4.

(3) They alleged that CVS Caremark "excluded [them] from participation in, … denied [them] the benefits of, or … subjected [them] to discrimination under" the Program, which disparately impacts them due to their disability. *See, e.g.* EOR 82–85, ¶¶ 142, 147.

Nothing more is needed to allege a Section 1557 discrimination claim. CVS Caremark must demonstrate they have reasonable medical or scientific evidence connected to the standard of care to justify their use of any discriminatory exclusion. *See* 81 Fed. Reg. 96, 31405 ("Scientific or medical reasons can justify distinctions

based on the grounds enumerated in Section 1557."). They cannot do so for purposes of opposing these allegations as a matter of law, and they made no attempt to do so in their motion to dismiss.

II. Appellants Adequately Pled Each Element Necessary to State a Section 504 Discrimination Claim Based on a Disparate Impact Theory

In addition to alleging a standalone violation of Section 1557, Appellants sufficiently allege a Section 504 violation and, therefore, an independent violation of Section 1557. The district court correctly recognized that "§ 504 case law serves as a *useful guide* for evaluating what kind of disability-based discrimination violates the ACA." EOR 187 (emphasis added). Because "federal financial assistance" as defined under Section 504 explicitly excluded private health insurance contracts, the protections of Section 504 did not apply to private health insurance plans prior to the ACA. Hence this Court must interpret and apply Section 504 case law in the context of the ACA. "Section 1557 of the ACA *extends* the protections of Section 504 of the Rehabilitation Act … *in the context of the ACA*." *Huffman v. Univ. Med. Ctr. Mgmt. Corp.*, 2017 WL 4960268, at *2 (E.D. La. Oct. 31, 2017) (emphasis added). This, among other reasons, is why "the ACA created a tectonic shift in the nation's health insurance market." *Molina Healthcare of California, Inc. v. United States*, 133 Fed. Cl. 14, 19 (2017).

Appellants properly alleged a Section 504 claim, as they alleged that: (1) they are individuals with a disability; (2) they are otherwise qualified to receive the

benefit; (3) they were excluded from participation in, denied the benefits of, or subjected to discrimination under the Program solely by reason of their disability; and (4) the Program receives federal financial assistance. EOR 83, 86–87 ¶¶ 153–54, 156–59. *See Duvall v. Cty. of Kitsap*, 260 F.3d 1124, 1135 (9th Cir. 2001), *as amended on denial of reh'g* (Oct. 11, 2001). "Section 504 protects persons with disabilities from both intentional and disparate–impact discrimination." EOR 187 (citing *Crowder*, 81 F.3d at 1484); *see also Alexander*, 469 U.S. at 295 ("Discrimination against the handicapped was perceived by Congress to be most often the product, not of invidious animus, but rather of thoughtlessness and indifference—of benign neglect."); *but see Doe v. BlueCross BlueShield of Tenn., Inc.*, slip op. at 8 (holding that disparate impact claims are not cognizable under Section 504). "In the context of disability …, equal treatment may not beget equality, and facially neutral policies may be, in fact, discriminatory if their effect is to keep persons with disabilities from enjoying the benefits of services that, by law, must be available to them." *Presta v. Peninsula Corridor Joint Powers Bd.*, 16 F. Supp. 2d 1134, 1136 (N.D. Cal. 1998).

This Court has long held that the distinction between "facial" and "disparate impact" discrimination is not the end of the analysis when addressing disability discrimination. *Crowder*, 81 F.3d at 1484 (holding facially neutral statute that disproportionately burdens the disabled and denies "meaningful access" because of

their unique needs remains actionable). "[I]t is more useful to assess whether disabled persons were denied 'meaningful access' to state provided services." *Id.* *See also Rodde v. Bonta*, 357 F.3d 988, 997 (9th Cir. 2004) (discussing *Alexander* and noting that "[t]he reduction at issue in *Alexander* was facially neutral" and "the proposed cutback in *Alexander* did not uniquely affect disabled individuals …" such that meaningful access was denied); *Mark H. v. Lemahieu*, 513 F.3d 922, 937 (9th Cir. 2008) (relying on *Crowder* and *Choate*); *McGary v. City of Portland*, 386 F.3d 1259, 1266–67 (9th Cir. 2004) (same).

The district court cited *Crowder* and *Alexander* in recognizing that a Section 504 disparate impact claim should be assessed under the "meaningful access" standard. However, because the extent of such discrimination is intensively fact-based, the district court erred in ruling that (1) Appellants cannot state a claim for disparate impact because the Program also applies to non–disabled individuals; (2) Appellants did not sufficiently allege they were disparately impacted relative to other enrollees by showing that the Program's impact on enrollees with HIV/AIDS is unique; and (3) the "impact [was] not so significant as to constitute a denial of 'meaningful access'" to their prescription drug benefits. EOR 188–190, 192–193.

A. The District Court Erred in Finding That the Program Is Not a Policy Upon Which a Disparate Impact Claim Can Be Premised

The district court erred in its conclusion that allegations that non-HIV/AIDS insureds are enrolled in the Program "'is fatal to Plaintiff[s'] claim'" that the Program results in a unique and disproportionate harm on insureds with HIV/AIDS. EOR 188 (citing *Doe v. BlueCross BlueShield of Tenn., Inc.*, 2018 WL 3625012, at *8 (W.D. Tenn. July 30, 2018), *aff'd*, No. 185897, slip op. (6th Cir. June 4, 2019)).

First, that the Program applies to both disabled and non-disabled individuals is a fact in favor of Appellants' disparate impact claim. A disparate impact claim exists where a facially neutral policy applies to both disabled and non-disabled individuals yet results in a unique harm due to the plaintiff's disability. *See K.M. ex rel. Bright v. Tustin Unified Sch. Dist.* ("*K.M.*"), 725 F.3d 1088, 1102 (9th Cir. 2013) ("[T]o challenge a facially neutral government policy on the ground that it has a disparate impact on people with disabilities, the policy must have the effect of denying meaningful access to public services."); *Crowder*, 81 F.3d at 1483–84 (explaining that barriers arise from policies that are "facially neutral but may work to effectuate discrimination against disabled persons" and observing that "Hawaii's quarantine requirement applies equally to all persons entering the state with a dog …"); *see also United States v. Cty. of Los Angeles*, No. 15-cv-05903, 2016 WL 2885855, at *4 (C.D. Cal. May 17, 2016) (rejecting defendant's argument that

intervenors "cannot possibly be discriminated against" because "all inmates are processed and released *in the same, evenhanded way*" and holding that "[i]ntervenors have adequately alleged that, as a result of their particular disabilities, they are denied meaningful access to discharge planning services") (emphasis added). Discrimination may be found to exist where a policy has the effect of "screening out" or limiting a class of individuals with disabilities "from fully and equally enjoying any service, program or activity." *Cota v. Maxwell-Jolly*, 688 F. Supp. 2d 980, 996 (N.D. Cal. 2010) (facially neutral policies or methods of administration that apply to all applicants do not insulate defendants from liability for disparate impact discrimination). Therefore, Appellants are not required to show that *only* disabled people are subject to the Program to demonstrate discrimination. The district court erred in so holding.

Second, the district court's reliance on *In re Express Scripts/Anthem ERISA Litig.*, 285 F. Supp. 3d. 655 (S.D.N.Y. 2018), *appeal docketed*, No. 18-346 (2d Cir., argued on Oct. 19, 2018), EOR 188–189, does not support its conclusion that Appellants cannot sustain their ACA claim because the Program applies to medications that treat individuals both with and without disabilities. In that case, the court found allegations of disparate impact under the ACA insufficient where plaintiffs alleged their health plan's *inflated drug pricing* disproportionately impacted HIV/AIDS patients who purchased certain medications and were subject

to a percentage based co-insurance payment. The court based its holding on its finding that those plaintiffs did not allege that the percentage–based co–insurance rates they actually paid for their HIV medication were higher than those for other, non–HIV related drugs. *Id*. at 686–88. Here, by contrast, Appellants *have alleged* the loss of meaningful access to their prescription drug benefit that disproportionately impacts them more than other enrollees. EOR 47, 83, 90–91, ¶¶ 92, 145, 172, 176.

B. The District Court Erred in Ruling Appellants Failed to Allege Disproportionate Harm to HIV/AIDS Patients

Concluding that "the allegations in the complaint are not sufficient to support Plaintiffs' claim that the Program's impact on enrollees with HIV/AIDS is 'unique,'" EOR 190 (citing *Rodde*, 357 F.3d at 998), the district court failed to properly consider Appellants' allegations that, because the complex prescription drug regimen and treatment for HIV/AIDS cannot be adequately provided under the Program, Appellants have been denied meaningful access to their prescription drug benefit.

Appellants alleged the Program has a unique and disproportionate impact on Appellants by (i) providing a prescription drug benefit in a manner that threatens their health and privacy due to the unique nature of HIV/AIDS, (ii) eliminating access to 85% of Network Pharmacies that HIV/AIDS patients would otherwise have access to but for their disability and which are uniquely essential to them, and

(iii) eliminating their ability to access knowledgeable pharmacists that are critical to their ongoing care—a benefit they would otherwise have, but for their disability. *E.g.*, EOR 38–42, ¶¶ 68–70, 73–76. Taken together, these allegations are sufficient to establish that the Program disproportionately impacts Appellants "in a manner different and greater than it burdens others." *Crowder*, 81 F.3d at 1484.

Appellants included specific allegations about the numerous ways in which CVS Caremark designed, implemented, and continues to operate the Program in a manner that inflicts unique and significant harms upon insureds with HIV/AIDS because of their disability. Inherent within its design, CVS Caremark's Program fails to deliver Appellants' life-sustaining medications in a timely and secure manner, resulting in delays and missed dosages of a critically necessary medication. EOR 30–37, 46, ¶¶ 46, 51, 55–56, 59–63, 66, 90. Disruptions in the delivery of their HIV/AIDS Medications uniquely impact and deny insureds with HIV/AIDS a benefit critical for the treatment of their disability. EOR 32–33, 36–37, 39–40, ¶¶ 51, 63, 66, 73. A missed dosage of their HIV/AIDS Medication can be life–threatening, EOR 32–33, 36–37, 46, ¶¶ 51, 63, 66, 89–90, or result in an increased "risk of developing [] drug resistance" EOR 32–33, 36–37, ¶ 51, 66; *see also id*. at ¶ 63. John Doe Four, for example, alleges that "[o]n several occasions, deliveries of critical [HIV/AIDS] medications have not arrived on time and/or have not arrived by the date specified by CVS Caremark for delivery." EOR 32–33, ¶ 51. These are

not isolated instances. EOR 30–31, 35–37, 46, ¶¶ 46, 59–63, 66, 90. On another occasion, when John Doe One's medication was delivered to his home through the Program's mail-order requirement, "he found his 90-day supply of HIV/AIDS Medication baking in the afternoon sun." EOR 23, ¶ 24. This is particularly harmful for people living with HIV/AIDS, as "[s]torage at high temperatures can quickly degrade the potency and stability of HIV/AIDS medications." *Id*.

Moreover, there are privacy concerns unique to HIV/AIDS patients who risk being stigmatized should their medical condition be inadvertently disclosed. EOR 24, 26–27, 38, 40, ¶¶ 28, 33, 37, 69, 74. Individuals have expressed alarm that neighbors and coworkers, who do not know of their HIV/AIDS status, will come to suspect that they are ill based on the receipt of packages containing medications. EOR 40–41 ¶ 74. Deliveries to CVS pharmacies raise similar privacy concerns. EOR 26, 40–42, ¶¶ 33, 74–76.

Loss of access to thousands of network pharmacies and knowledgeable pharmacists also has a disproportionate impact on people with HIV/AIDS compared to nondisabled consumers subject to the Program because, due to the unique nature of their illness, individuals like Appellants depend on "pharmacists to maximize the benefits of HIV/AIDS Medications and to treat the complex and everchanging needs of HIV/AIDS patients." EOR 31, 33, 36–37, ¶¶ 47, 54, 64. Appellants have further alleged that, unlike other consumers who receive prescription drug benefits from

CVS Caremark who are not enrolled in the Program or other consumers without HIV/AIDS who are subject to the Program, Appellants uniquely rely on pharmacists as a critical member of their care team. Consultations with knowledgeable pharmacists are essential to "detect[ing] potentially life-threatening adverse drug interactions and dangerous side effects" unique to insureds with HIV/AIDS. EOR 38–39, ¶ 70. This "is vitally important for HIV/AIDS patients" to manage "problems that can arise while living with and managing HIV/AIDS" … "even as compared to patients taking other 'specialty' medications." EOR 43–44, ¶ 80. Access to pharmacists who do more than simply fill prescriptions and disburse medications is critically necessary; Appellants rely on pharmacists to "impart critical information about prescription drug regimens and warnings about … adverse side effects and adverse drug interactions associated with HIV/AIDS Medications that need to be monitored," *id.*, and to "provide essential advice and counseling that help HIV/AIDS patients and families navigate the challenges of living with a chronic and sometimes debilitating condition." EOR 38–39, ¶ 70.

This denial of access is further compounded because, by the design of the Program, CVS Caremark does not "have a full and accurate record of all of the medications" Appellants are taking and therefore "cannot anticipate or warn against potential adverse drug interactions, which are common with HIV/AIDS Medications." EOR 24, 41–42, ¶¶ 26, 75. Thus, despite the medical necessity of

such consultations for individuals with HIV/AIDS, under the Program this benefit is *nonexistent* for people such as Appellants. EOR 23–24, 38, 41–42, 44, ¶¶ 25, 69, 75, 81.

These allegations are sufficient to assert a Section 1557 claim, as Appellants aver that the design and operation of the Program, and its prohibition against accessing Network Pharmacies and pharmacists, inflicts unique harms on Appellants due to the complex nature of HIV/AIDS and the unique needs of people with HIV/AIDS. For example, in *Rodde v. Bonta*, 357 F.3d at 997, 998, reasoning that the "County's planned cutback specifically targets services for the disabled," this Court affirmed the district court's conclusion that "the [hospital] closure [] would deny certain disabled individuals meaningful access to government-provided services *because of their unique needs*, while others would retain access to the same class of services." (emphasis added). Similarly, in *Crowder v. Kitagawa*, 81 F.3d at 1484–85, finding a "unique dependence upon guide dogs among many of the visually-impaired," this Court held that Hawaii's quarantine requirement denied the plaintiffs "meaningful access to state services, programs and activities by reason of their disability …". *See also Communities Actively Living Indep. & Free v. City of Los Angeles* ("*CALIF*"), No. 09-cv-0287, 2011 WL 4595993, at *14 (C.D. Cal. Feb. 10, 2011) (granting plaintiffs' summary adjudication motion on ADA and Section 504 claims because plaintiffs "require special needs [due to their disability], [and]

the City disproportionately burdens them through its facially neutral practice of administering its program in a manner that fails to address such needs"); *Cty. of Los Angeles*, 2016 WL 2885855, at *4 (intervenors adequately alleged prisoners with certain types of mental health disabilities were denied "meaningful, state-provided discharge services" due to their particular disabilities).

C. Appellants Are Denied Meaningful Access to Their Prescription Drug Benefits

The district court also erred in concluding that Appellants did not adequately allege facts to support an inference that insureds with HIV/AIDS are denied meaningful access to their prescription drug benefit under the Program because the impact is not "significant" enough. EOR 190. The district court found as a matter of law that "the obstacles … to obtain their HIV/AIDS Medication under the Program, while understandably a source of frustration and stress, do not rise to a level that deprives Plaintiffs of 'meaningful access' to their benefits." EOR 192. The district court's conclusion on this point was error on several grounds.

First, the critical step in a court's meaningful access analysis is how the challenged benefit is defined. As the *Alexander* Court presciently warned, "[a]ntidiscrimination legislation can obviously be emptied of meaning if every discriminatory policy is 'collapsed' into one's definition of what is the relevant benefit." *Alexander*, 469 U.S. at 301 n.21. Courts must be scrupulous and precise when addressing the issue of defining the benefit. *Id*. ("The benefit itself, of course,

cannot be defined in a way that effectively denies otherwise qualified handicapped individuals the meaningful access to which they are entitled …").

Here, the district court incorrectly limited the benefit to "HIV/AIDS medication for *favorable prices* at non-CVS pharmacies" or "at *favorable prices* outside the Program's network." EOR 186, 191 (emphasis added). However, when properly construed, the "benefit" that Appellants allege they are denied meaningful access to is not favorable pricing, but the prescription drug benefit as a whole, which includes (1) dispensing of HIV/AIDS Medications in a medically–appropriate manner and (2) actual access to Network Pharmacies and pharmacists that provide medically necessary counseling. Specifically, "[b]ut for the Program," Appellants and others similarly situated would have access to thousands of pharmacies and pharmacists who "would be aware of the patient's entire medical history, have a comprehensive view of the patient's complete medication load (as compared to only certain specialty medications), and engage in on-going communications with physicians and patients regarding potential issues that may arise concerning drug side effects, adverse drug interactions, and adherence to specialty medications." EOR 44, ¶ 82. These aspects of the prescription drug benefit are available for medications not subject to the Program used to treat nondisabled enrollees. Appellants sufficiently alleged a denial of meaningful access, as CVS Caremark's actions "tend to exclude HIV/AIDS patients from full participation in health care

plans where the prescription benefit is administered by CVS Caremark …" EOR 83–84, ¶ 146. As the "benefit" construed by the district court is not what Appellants actually alleged, this Court must reverse the district court's conclusion. *See Grangetto v. Minn*, No. 10-cv-0701, 2011 WL 386855, at *1 (E.D. Cal. Feb. 3, 2011) ("The court must also assume that general allegations embrace the necessary, specific facts to support the claim.") (citing *Smith v. Pacific Prop. and Dev. Corp.*, 358 F.3d 1097, 1106 (9th Cir. 2004)).

Second, the district court erred in applying an overly restrictive "meaningful access" standard to Appellants' allegations. The district court's meaningful access analysis would effectively require Appellants to allege a complete deprivation or denial of access to a benefit in order to state a claim of disparate impact under Section 504. Citing to only *Crowder* and *Rodde*, the district court held as a matter of law that "[c]ases finding a denial of meaningful access have required *significantly more severe deprivations*" than alleged in the Complaint. EOR 192 (emphasis added). However, *Crowder* and *Rodde* do not stand for the proposition that a Section 504 plaintiff must allege a complete deprivation of access to a program or benefit. Neither plaintiff in these cases were found to have experienced a complete deprivation or denial of access to a program benefit. Rather, the factual finding based on the meaningful access standard was whether the defendants' actions prohibited the plaintiffs from meaningfully benefitting under the service or program

or having their needs adequately served–factually intensive determinations that should not have been resolved on a motion to dismiss. *See Crowder*, 81 F.3d at 1482 ("[T]he state's quarantine requirement denies visually-impaired persons the ability to make *meaningful use of services* the state provides. … Without their dogs to guide them, the plaintiffs are *severely restricted* in their ability to use state services.") (emphasis added). In *Rodde*, 357 F.3d at 997–98, this Court found that if the county closed the hospital at issue, "it will *reduce*, and in *some instances* eliminate, necessary medical services for disabled Medi-Cal patients …") (emphasis added). The *Rodde* Court ultimately concluded that "[w]hile the disabled could theoretically seek service from the remaining facilities, the evidence suggested … that the services … would not *adequately serve the unique needs of the disabled*, who therefore would be effectively denied services that the nondisabled continued to receive." *Rodde*, 357 F.3d at 998 (emphasis added). *See also Alexander*, 469 U.S. at 302 ("[N]othing in the record suggests that the handicapped in Tennessee will be unable to *benefit meaningfully* from the coverage they will receive under the 14-day rule."); *id*. at 302 n.22 (A practice that impedes a medical condition "*occurring with greater frequency among*" certain individuals with disabilities from being "effectively treated, at least in part," could constitute a denial of meaningful access.) (emphasis added).

A recipient of federal financial assistance must do more than provide individuals with disabilities mere access to the benefits it offers. 45 C.F.R. §§ 84.4(b)(1)(ii)–(iii) (relevant excerpts attached as Addendum J); *see also Alexander*, 469 U.S. at 301 ("[A]n otherwise qualified handicapped individual must be provided with *meaningful* access to the benefit that the grantee offers.") (emphasis added); *Bassilios v. City of Torrance, CA*, 166 F. Supp. 3d 1061, 1071 (C.D. Cal. 2015) ("Section 504 require[s] that disabled persons receive 'meaningful access' [to a benefit], not merely 'limited participation.'").

In this Circuit, it is well recognized that meaningful access is denied when a policy disproportionately harms individuals with a disability such that it inadequately accounts for their specific needs and effectively reduces their access to services, programs, or activities. For example, in *M.S. v. Cty. of Ventura*, 2017 WL 10434015, at *18–19 (C.D. Cal. Mar. 7, 2017), the court denied defendant's motion to dismiss plaintiffs' Section 504 disparate impact claim alleging defendants failed to provide mental health services *in a reasonable time*. Similarly, in *Scott v. Garcia*, 370 F. Supp. 2d 1056, 1075 (C.D. Cal. 2005), the district court denied defendants' motion for summary judgment on an inmate's claim he was denied meaningful access to the Department of Correction's prison food service where he was not permitted *sufficient time* to eat his meals. *See also Cal. Found. for Indep. Living Ctrs. v. City of Sacramento*, 142 F. Supp. 3d 1035, 1065 (E.D. Cal. 2015) ("A policy

may deny meaningful access by imposing a *disproportionate burden* on the disabled.") (emphasis added). In each of these cases, the "meaningful access" standard was not one of complete deprivation or denial of access to a benefit, but whether an individual with a disability would be unable to benefit reasonably and meaningfully based on all the relevant circumstances.

While courts "need not define precisely the severity of the deprivation that a plaintiff must experience in accessing a program benefit … to demonstrate a denial of meaningful access," *Am. Council of the Blind v. Paulson*, 525 F.3d 1256, 1269 (D.C. Cir. 2008), courts have routinely recognized that "[a]ccess alone, despite defendants' arguments to the contrary, is insufficient." *Marisol A. by Forbes v. Giuliani*, 929 F. Supp. 662, 685 (S.D.N.Y. 1996) (citing *Alexander*, 469 U.S. at 301), *aff'd sub nom.* 126 F.3d 372 (2d Cir. 1997). In *Marisol A.*, 929 F. Supp. at 684, the court rejected defendants' argument that plaintiffs' ADA and Section 504 claims should be dismissed because they still had the opportunity to participate in foster care services, since plaintiffs alleged the city agency failed to provide a child with HIV/AIDS "proper medical attention to allow [him] to function while in foster care …" *Id*. (finding plaintiffs sufficiently alleged a denial of meaningful access to New York City's child welfare system). *Accord Henrietta D. v. Giuliani*, 119 F. Supp. 2d 181, 207 (E.D.N.Y. 2000), *aff'd sub nom. Henrietta D. v. Bloomberg*, 331 F.3d 261 (2d Cir. 2003) (City denied individuals with HIV/AIDS meaningful access to

public assistance program because "[a]s the Second Circuit has observed, '[i]t is not enough to open the door for the handicapped …; a ramp must be built so the door can be reached.'")

HHS regulations implementing the ACA further help to specifically define what constitutes meaningful access to prescription drug benefits, providing that Appellants must be able to obtain their medications at all network pharmacies. 45 C.F.R. § 156.122(e); *see also Cal. Council of the Blind*, 985 F. Supp. 2d at 1236 ("[W]hen considering the 'meaningful access requirement,' courts in the Ninth Circuit are guided by the specific implementing regulations of the [statute at issue].") (citing *K.M.*, 725 F.3d at 1102). Accordingly, a PBM cannot single out a benefit that Appellants disproportionately rely on–access to their HIV/AIDS Medications at Network Pharmacies from knowledgeable pharmacists that nondisabled individuals are afforded–"because of their unique needs" and effectively reduce access to the benefit. *Rodde*, 357 F.3d at 998; *see Alexander*, 469 U.S. at 301, 302 n.22; *see also* 45 C.F.R. §§ 84.4(b)(1)(ii)–(iii), (b)(4) (Recipients of federal financial assistance "may not, directly or through contractual or other arrangements, utilize criteria or methods of administration … that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program or activity with respect to handicapped persons …"). Yet, as set forth above, this is exactly what CVS Caremark has done here. Consequently, "Class Members have

not been provided meaningful access to their life-sustaining medications …" EOR 83, ¶ 145. The Program ultimately "reduces the overall quality of care Class Members receive and reduces or effectively eliminates their health plans' pharmacy benefit …" EOR 45, ¶ 87. Thus, even assuming Appellants must allege a complete denial of access to their prescription drug benefit to state a Section 504 claim under *Alexander* (which Appellants do not concede they are required to do), such allegations clear this hurdle.

III. Appellants Adequately Pled Discriminatory Treatment Under Section 504 and the Unruh Act on a Failure-to-Accommodate Theory

The district court also erred in dismissing Appellants' discriminatory treatment claims based on its finding that the allegations were "insufficient to support an intentional discrimination claim under § 504 … [and] the Unruh Act" and were "wholly conclusory and undermined by the complaint's descriptions of accommodations CVS made to assist Plaintiffs in accessing their HIV/AIDS medications." EOR 187, at n.4.

There are no allegations that the Appellees tried to assist Appellants in any way or make any reasonable accommodation. To the contrary, Appellants each requested that CVS Caremark provide a reasonable accommodation in the form of being permitted to access the same Network Pharmacies that other enrollees not subject to the Program may access. At no point following Appellants' requests for reasonable accommodations did any of the defendants engage in any meaningful

interactive process or attempt to obtain any form of accommodation for them. EOR 23–24, 28–30, 35–36, ¶¶ 22–23, 27, 40–41, 45, 61–62. In fact, as alleged in the Complaint, every appeal or request for accommodation due to their specific needs was ignored by all Appellees. *Id.*

A. CVS Caremark Unlawfully Refused Appellants' Reasonable Accommodation Requests

"[I]n order to state a failure to accommodate claim with 'facial plausibility,' each Plaintiff must allege the reasonable accommodation(s) he or she requested, and that Defendant refused the accommodation(s)." *Moore v. Equity Residential Mgmt., L.L.C.*, No. 16-cv-07204, 2017 WL 2670257, at *3 (N.D. Cal. June 21, 2017); *see Vinson*, 288 F.3d at 1154 (setting forth elements for a reasonable accommodation claim under Section 504); *Fortyune v. Am. Multi-Cinema, Inc.*, 364 F.3d 1075, 1082–84 (9th Cir. 2004) (similar). There are similar pleading requirements under the Unruh Act. *See Phillips v. P.F. Chang's China Bistro, Inc.*, No. 5:15-cv-00344, 2015 WL 7429497, at *6 (N.D. Cal. Nov. 23, 2015) (denying motion to dismiss Unruh Act claim where the plaintiff alleged restaurant intentionally discriminated by failing to provide reasonable accommodation, citing federal law).

Appellants have alleged that the Program's requirements prevent them from effectively accessing and utilizing their prescription drug benefits due to their disability and the treatment necessary for the maintenance of their health; that they requested a reasonable accommodation to the Program's requirements; that all such

requests were denied and, consequently, Appellants have been denied meaningful access to their prescription drug benefit. EOR 19–20, 23–24, 28–29, 39, ¶¶ 9–11, 23, 27, 40–41, 71.

These allegations are sufficient to state a claim of reasonable accommodation discrimination under both Section 504 and the Unruh Act. *See e.g.*, *McGary*, 386 F.3d at 1269 (City's denial of "additional time to participate in the nuisance abatement program without incurring charges" was sufficient to allege a failure–to–accommodate claim); *Gladle v. Shulkin*, 700 F. App'x 742 (9th Cir. 2017) (alleged failure to participate in an interactive process in response to plaintiff's reasonable accommodation request was sufficient to state a claim under Section 504); *see also Phiffer v. Oregon*, No. 10-cv-1120, 2011 WL 7396602, at *4 (D. Or. Nov. 21, 2011) (allegations that "but for the failure to make accommodations for his disability, [plaintiff] would have been able to enjoy the ordinary protections of the court without the accompanying pain and suffering" was sufficient to allege discrimination under Section 504); *D.R. ex rel. Courtney R. v. Antelope Valley Union High Sch. Dist.*, 746 F. Supp. 2d 1132, 1145 (C.D. Cal. 2010) (granting preliminary injunction where student could not "participate in extracurricular activities to the same extent as other students" because of her disability and "the inadequate accommodation provided by the Defendant").

B. One-Time Exceptions Cannot Immunize CVS Caremark From Allegations of Failure-to-Accommodate Discrimination

Despite the allegations detailed above, the district court found "the allegations of intentional discrimination are undermined by references in the Complaint to instances where CVS made accommodations or assisted Plaintiffs in accessing their prescription drug benefits." EOR 197. As noted above there are no such allegations. The alleged "accommodations" cited by the district court simply refer to CVS Caremark's one-time exemptions providing short delays in initially implementing the Program; once the Program was implemented, however, *no changes* were made to ameliorate its harmful, ongoing impacts on Appellants. A "one-time exception" allowing John Doe Three's local pharmacy to fill his HIV/AIDS Medications, which CVS Caremark never permitted again, and "sending a same day courier with [John Doe Five's] HIV/AIDS Medications," because he "did not receive his medication as ordered through the CVS Specialty website," EOR 29–30, 35, ¶¶ 43, 60, were one–time acts – not comprehensive reasonable accommodations. The actions by CVS Caremark did not provide any relief from the root cause of the problem.

CALIF, 2011 WL 4595993, at *14, is instructive on this issue. There the plaintiffs alleged that the city failed to provide for the unique needs of individuals with disabilities in its emergency preparedness program. Rejecting defendant's defense "that it can make *ad hoc* reasonable accommodations upon request," the court found such contentions "both legally inadequate and practically unrealistic."

Id. Similarly, Appellees' rejected requests to assist Appellants in accessing their prescription drug benefit following these *ad hoc* one-time exceptions supports a finding that the supposed "modifications" to the Program did not actually accommodate Appellants' disability.

Both *Wilkins-Jones v. Cty. of Alameda*, 859 F. Supp. 2d 1039 (N.D. Cal. 2012), and *Greater Los Angeles Agency on Deafness, Inc. v. Cable News Network, Inc.*, 742 F.3d 414 (9th Cir. 2014), which the district court relied upon to reach its conclusion, are inapposite. In *Wilkins-Jones*, 859 F. Supp. 2d at 1052, the defendants "provided some, but not all, accommodations" that the plaintiff requested. There was also an absence of allegations that the plaintiff "directly asked … for any particular accommodation which was refused or that her disabilities warranting such additional accommodations were obvious and should have been known by [defendants]." *Id*. The one-time acts of CVS Caremark are factually distinguishable from the reasonable accommodations at issue in *Wilkins-Jones*. Moreover, following these *ad hoc* onetime exceptions, CVS Caremark continued to refuse all reasonable accommodation requests to assist Appellants in accessing their prescription drug benefits. EOR 30, 35–36, ¶¶ 45, 61–62. Thus, contrary to *Greater Los Angeles Agency on Deafness*, 742 F.3d at 426, there are no allegations of CVS Caremark being "'ready to provide whatever … access is ultimately required'" to ensure Appellants are provided meaningful access to their prescription drug benefit.

C. The District Court Erred in Prematurely Ruling the Accommodation Appellants Sought Was a Fundamental Change

In ruling that "[a]t bottom, Plaintiffs are seeking to change the terms of their benefit plan so that they … can obtain their HIV/AIDS medication from non-CVS pharmacies at in-network prices," EOR 191–192, the district court erred by misconstruing Appellants' factual allegations and conflating the court's policy concerns with Appellants' pleading requirements. Appellants only seek to obtain their HIV/AIDS Medications from the same Network Pharmacies they were able to use prior to the implementation of the Program, and where other enrollees not subject to the Program may currently obtain their medications.

"'[I]t is enough for the plaintiff to suggest the existence of a plausible accommodation, the costs of which, facially, do not clearly exceed its benefits,' and once this is done 'the risk of non-persuasion falls on the defendant.'" *Charles Anthony Guerra, et al. v. W. Los Angeles Coll., et al.*, No. 16-cv-6796, 2017 WL 10562682, at *8 (C.D. Cal. June 14, 2017) (citing *Disabled in Action v. Bd. of Elections in the City of New York*, 752 F.3d 189, 202 (2d Cir. 2014); *see also Mark H. v. Hamamoto*, 620 F.3d 1090, 1097–98 (9th Cir. 2010). Appellants have made such allegations in the Complaint.

First, whether a reasonable accommodation is a fundamental alteration is an affirmative defense, not raised by CVS Caremark. Moreover, such a defense requires a fact-specific inquiry that is inappropriate on a motion to dismiss. "In

particular, courts evaluating fundamental alteration defenses must take into account financial and other logistical limitations on a [defendant's] capacity to provide integrated services to the disabled …" *M.S.*, 2017 WL 10434015, at *19 (quoting *Townsend*, 328 F.3d at 519). Thus, "it would be inappropriate to decide whether [the accommodation] would fundamentally alter the nature of its programs at the motion to dismiss stage." *Id.*; *see also Hamamoto*, 620 F.3d at 1098 ("'[M]ere speculation that a suggested accommodation is not feasible falls short of the reasonable accommodation requirement; [Section 504] create[s] a duty to gather sufficient information from the disabled individual … to determine what accommodations are necessary.'"); *Cal. Council of the Blind v. Cty. of Alameda*, 985 F. Supp. 2d 1229, 1240 (N.D. Cal. 2013) ("Defendants do not argue … [a] fundamental alteration [defense]. Nor should they on a motion to dismiss, in light of the fact they bear the burden of proof on this point."). Here, the district court should have carefully reviewed the structure of CVS Caremark's pharmacy network, Appellants' prescription drug benefit, the broad, remedial purpose of the ACA, the evidence of alleged discrimination, and the possible remedies to reach a conclusion on this affirmative defense. *See Alexander*, 46 U.S. at 307–08. Such an analysis is beyond the reach of a motion to dismiss. At a minimum, the district court should have granted Appellants leave to amend to allege sufficient detail regarding this claim.

Second, to remedy the denial of meaningful access to their prescription drug benefit, the accommodation sought by Appellants is not access to their HIV/AIDS Medications for favorable prices at *any* non-CVS pharmacies as the district court incorrectly found, but access to the same Network Pharmacies to which other enrollees not subject to the Program have access. *See, e.g.*, EOR 19–20, 23–24, 28–30, 39, 72, ¶¶ 9–13, 23, 27, 40–41, 45, 71, 102. Thus, the district court's speculation that if Appellants' claims were to proceed "[t]he logical extension of Plaintiffs' discrimination challenge could threaten the basic structure of Health Maintenance Organizations ('HMOs') and Preferred Provider Organization insurance plans ('PPOs')," EOR 192, reflects a misunderstanding of the accommodation sought by Appellants.

IV. The District Court Erred in Dismissing Appellants' ADA Claim

A. The Correct "Place of Public Accommodation" Alleged by Appellants Is CVS Caremark's Network Pharmacies, Not the Plans

The ADA prohibits discrimination based on disability "by any person who owns, leases (or leases to), or operates a place of public accommodation." 42 U.S.C. § 12182. Unlawful discrimination under the ADA includes both physical and intangible barriers to accessing a place of public accommodation. *Rendon v. Valleycrest Prod., Ltd.*, 294 F.3d 1279, 1283 (11th Cir. 2002); *see also* 42 U.S.C. § 12182(2)(A)(i)–(iii) (statutory language describing intangible barriers) and *Nat'l*

Fed'n of the Blind v. Target Corp., 452 F. Supp. 2d 946, 954 (N.D. Cal. 2006) (discussing *Rendon*).

Appellants sufficiently alleged how CVS Caremark engaged in acts of discrimination in violation of the ADA. In the Complaint at ¶¶ 153, 157, 159–164, Appellants alleged how the Program denies them and other similarly affected individuals the services provided by Network Pharmacies, which are defined by 42 U.S.C. § 12181(7)(F) as "place[s] of public accommodation." EOR 86-89. Appellants have also sufficiently alleged that CVS Caremark effectively "operates" the network pharmacies through contracting and financial incentives, and denies Appellants access to these places of public accommodation on the basis of their disability. EOR 43, 88, 96–97, ¶¶ 79, 162, 205.

The district court correctly acknowledged that CVS Caremark operates the Network Pharmacies for purposes of the ADA due to its contractual relationship designating those pharmacies as in–network. EOR 194; *see also Zamora-Quezada v. HealthTexas Med. Group of San Antonio*, 34 F. Supp. 2d 433, 444 (W.D. Tex. 1998) ("The term operates for the purposes of the ADA means a right to control the allegedly discriminatory conditions.") (citing *Neff v. Am. Dairy Queen Corp.*, 58 F.3d 1063, 1066 n.9 (5th Cir. 1995)) and *Lentini v. California Ctr. for the Arts, Escondido*, 370 F.3d 837, 846 (9th Cir. 2004). However, the district court erred in finding that "it is of no moment that the Plaintiffs allege CVS 'exercise[s] their direct

and contractual control over establishing which pharmacies are available to Plaintiffs,' … because 'Title III does not address the terms of the policies that [a benefit plan administrator] sells.'" EOR 194 (citing *Weyer*, 198 F.3d at 1107). Notably, Appellants do not allege the healthcare benefit plan is the "place of public accommodation" at issue. In beginning its analysis by accepting Appellees' argument that the place of public accommodation is "Plaintiffs' *benefit plan*," EOR 193, the rest of the district court's analysis was erroneous.

The district court held that no ADA violation lies as a matter of law because, as it claims *Weyer* notes, "Title III does not address the terms of the policies that [a benefit plan administrator] sells. …" EOR 194 (citing *Weyer*, 198 F.3d at 1115). The district court improperly applied the ruling in *Weyer*. Neither *Weyer* nor the authorities cited by *Weyer* negate the principle that the ADA's prohibition against discrimination applies to a private entity that operates a place of public accommodation—in this case, a pharmacy. Here, the Complaint includes detailed allegations how the Program denied Appellants full access to and enjoyment of the Network Pharmacies. EOR 86–89, ¶¶ 153, 157, 159–164.

The *Weyer* court affirmed dismissal of the plaintiff's ADA claims because the plaintiff failed to allege any "nexus" between the alleged discrimination and a place of public accommodation. In *Weyer*, the plaintiff sued an insurance company under the ADA because her policy provided more benefits for physical disabilities than for

mental health disabilities. *Weyer*, 198 F.3d at 1107. The plaintiff claimed the "place of public accommodation" she was being denied access to was the insurance company's *office*. *Id.* The Ninth Circuit rejected that theory, concluding that plaintiff's true theory of liability was based solely on the terms of her benefit plan, without any actual denial of access to a "place of public accommodation." *Id.* *Weyer* only stands for the well-settled proposition that "the term 'place of public accommodation' require[s] a connection between the good or service complained of and an actual physical place." *Chabner v. United of Omaha Life Ins. Co.*, 225 F.3d 1042, 1047 (9th Cir. 2000) (citing *Weyer*, 198 F.3d at 1114).

In *Weyer* this Court relied heavily on an *en banc* decision from the Sixth Circuit in *Parker v. Metro. Life Ins. Co.*, 121 F.3d 1006 (6th Cir. 1997). In *Parker*, the Sixth Circuit held the plaintiff failed to allege a "nexus" between the disparity in benefits resulting from the challenged policy cap on mental health benefits under a long-term disability plan and any place of public accommodation. *Parker*, 121 F.3d at 1011. The plaintiff's ADA claim in *Parker* failed not because an insurance policy benefit was at issue, but because the plaintiff alleged the "place of public accommodation" in question was, as in *Weyer*, the insurance company office, and therefore there was "no nexus between the disparity in benefits and the services which [defendant] offers to the public from its insurance office." *Id.* This is simply

not the situation here, where Plaintiffs have adequately alleged a nexus between a denial of access to services and ADA-recognized "places of public accommodation."

Instead of inapplicable rulings such as *Weyer*, the reasoning of *Zamora-Quezada*, 34 F. Supp. 2d 433, which upheld an ADA claim under similar factual conditions as those alleged here, is more relevant and instructive. The *Zamora-Quezada* plaintiffs alleged the defendant insurance companies "delayed or denied them full and equal enjoyment of medical treatment and services in violation of the ADA" by effectively denying access to doctors' offices (the places of public accommodation) that were excluded from the insurance companies' networks. *Id.* at 439. "It was the health care delivery system in which the Humana defendants were participants, and particularly the financial arrangements which fueled the system, which controlled the delivery of health care and caused the acts of alleged discrimination about which plaintiffs complain." *Id*. at 444. The *Zamora-Quezada* court found that "[t]he term operates for the purposes of the ADA means a right to control the allegedly discriminatory conditions." *Id.* Accordingly, "[t]he relevant inquiry is whether Humana had control over the actions alleged to have resulted in the discrimination charged." *Id.* The court concluded the plaintiffs' allegations of delayed and denied access to care resulting from Humana's control over access to healthcare providers were sufficient to state an ADA claim. *Id.* There is no

functional difference between being denied access to doctors' offices and being denied access to pharmacies and the pharmacists who work there.

B. Appellants Sufficiently Alleged That the Program Discriminates on the Basis of Their Disability

As the district court correctly noted, to prevail on the ADA claim, Appellants need to plead that "(1) [they are] disabled within the meaning of the ADA; (2) the defendant is a private entity that owns, leases, or operates a place of public accommodation; and (3) the plaintiff[s] w[ere] denied public accommodations by the defendant because of [their] disability." EOR 193 (citing *Molski v. M.J. Cable, Inc.*, 481 F.3d 724, 730 (9th Cir. 2007)). As noted above, Appellants have sufficiently alleged all of these elements in the Complaint at ¶¶ 152–69.[11] EOR 86-89.

The district court also erred in concluding that Appellants failed to allege discrimination "on the basis of disability," EOR 194–96, holding that Appellants were required to allege an "intent" element as part of their ADA claim. The district

[11] The Court cited a Second Circuit case for the proposition that "the subterfuge clause in [§ 12201(c)] should be construed … to require an intent to evade." EOR196 (citing *Cervantes v. Countrywide Home Loans, Inc.*, 656 F.3d 1034, 1041 (9th Cir. 2011). However, Appellants have sufficiently alleged an ADA discrimination claim *regardless* of the allegations regarding subterfuge. Appellants do not rely solely on the subterfuge clause for its theory of liability; these allegations only underscore the extent of the discrimination that occurred. However, that is part of this claim.

court found that "[w]ithout more specific factual allegations supporting the inference that CVS intentionally compiled the specialty formulary to discriminate against persons with disabilities while evading accountability under the ADA, Plaintiffs have not made a sufficient showing that the Program discriminates on the basis of disability." EOR 196.

The district court cited no authority that the ADA requires a showing of "intentionality." In fact, the decisions cited by the district court (including *Lentini*, 370 F.3d at 846) stand for the exact opposite proposition: "Actionable discrimination can therefore take the form of 'outright intentional exclusion' as well as 'the discriminatory effects of … failure to make modifications to existing facilities and practices, exclusionary qualification standards and criteria, segregation, and relegation to lesser services, programs, activities, benefits, jobs, or other opportunities.'" EOR 195.

Relatedly, the district court also erroneously held that "insurance distinctions that apply equally to all employees cannot be discriminatory." EOR 195 (citing *Weyer*, 198 F.3d at 1116). *Weyer*, 198 F.3d at 1117, decided prior to the ACA, considered an employer's offering to all employees the chance to buy an optional fringe benefit disability policy—it was in this regard that the *Weyer* court concluded that "there is no discrimination under the Act where disabled individuals are given the same opportunity as everyone else … [The employer-defendant] did

not treat Weyer any differently because of her disability." *Id.* Such is not the case here. Appellants' ADA claim is not based, as in *Weyer*, on a healthcare plan that was equally offered as an optional fringe benefit to the disabled and nondisabled. Rather, it is Appellants' contention that the Program's design has a discriminatory effect on those with disabilities.[12] Appellants are not given the same opportunity to access prescription drugs as other enrollees.

Further, tracing the "apply equally to" language to its origin demonstrates how the district court misconstrued its import. That language was from *Ford v. ScheringPlough Corp*., 145 F.3d 601 (3d Cir. 1998), which in turn cited *Krauel v. Iowa Methodist Med. Ctr.*, 95 F.3d 674, 677–78 (8th Cir. 1996). However, the *Krauel* court's discussion of the type of insurance distinctions that are actionable under the ADA is actually consistent with Appellants' argument: "'A term or provision is 'disability-based if it singled out a particular disability … *a discrete group of disabilities … or disability in general* (*e.g.*, noncoverage of all conditions that substantially limit a major life activity).'" *Krauel*, 95 F.3d 674, 677–78 (citing EEOC: Interim Enforcement Guidance on Application of ADA to Health Ins., (June

[12] As the district court points out, in many situations, "There is no significant difference in the analysis of the rights and obligations created by the ADA and the Rehabilitation Act." EOR195, n. 7. As the ACA expressly prohibits discrimination in the *design* of insurance plan benefits as part of its access-expanding goals (*see* Section I, *supra*), in keeping with this sentiment, the Court should consider potential ADA violations through the same lens.

8, 1993)) (emphasis added). Plaintiffs contend that the Program *does* single out disabled enrollees, as nearly all the medications subject to it are prescribed to treat disabilities. *See, e.g.*, EOR 48, ¶ 94, n. 8.

In any case, the district court's interpretation of this language explicitly runs afoul of Supreme Court precedent holding that ADA claims based on disparate impact, which, by definition, involve a facially-neutral policy that applies to all, are cognizable. *See generally Raytheon Co. v. Hernandez*, 540 U.S. 44, 52–53 (2003) (discussing differences between disparate treatment and disparate impact discrimination claims under the ADA). The district court's finding that a neutral policy cannot, as a matter of law, be discriminatory is therefore clear error.

V. Appellants Properly Alleged a Denial-of-Benefits Claim Under ERISA and Declaratory Relief Because There Were No Allegations or Evidence That the Plans Were Validly Amended to Implement the Program

Appellants claimed that the implementation of the Program foreclosing their access to HIV/AIDS Medications through Network Pharmacies worked an unlawful reduction in their benefits due under their plans, giving rise to a claim for benefits due under Section 502(a)(1)(B) of ERISA. The district court dismissed this claim on the grounds that Appellants had not alleged a specific plan term entitling them to access their medications through independent pharmacies, stating that while "Plaintiffs 'had *previously* been able to obtain' medications from community

pharmacies … [t]hey do not allege that under the Program, they are *still* entitled to the same benefit." EOR 213.

The district court's dismissal of Appellants' claim conflated two separate concepts: the "Plan" and the "Program." Each Appellant alleged that he was covered by an employee welfare benefit plan. EOR 16, 22–23, 25, 29–30, 32, 34–35, 94, ¶¶1 n. 2, 20, 31, 43, 50, 58, 195. Such a plan is governed by ERISA. 29 U.S.C. § 1002(1)(A). Appellants' benefit plans are the "Plans" at issue here. The "Program" is a set of requirements that Plan members obtain HIV/AIDS Medications only by mail-order or drop-shipment to a CVS-branded pharmacy. EOR 16–17, ¶ 1.

The distinction between the Plan and the Program is important because the only way for the Employer-Appellees (Amtrak, Lowes, and Time Warner) to implement the Program (or any other change to the Plan) is through a valid amendment to the Plan. Section 402(b)(3) of ERISA provides that every employee benefit plan shall "provide a procedure for amending such plan, and for identifying the persons who have authority to amend the plan." 29 U.S.C. § 1102(b)(3). Appellants never alleged that the Plans were validly amended; in fact, they alleged the opposite—that implementation of the Program "caus[ed] a reduction in or elimination of benefits *without a change in actual coverage*[.]" EOR 94, ¶ 196. (emphasis added). Despite a few references in their briefing to an "amendment," Appellants never conceded this point in their oppositions to the motions to dismiss,

and they specifically argued to the district court that "we have never alleged that the plans were validly amended to include the [P]rogram." EOR 161.

Moreover, despite putting several Plan documents into the record, the Employer-Appellees never submitted any documents establishing a valid amendment. Amtrak submitted no relevant documents at all. Lowe's submitted an amendment to its prescription services agreement with CVS Caremark, which describes the Program, but it does not cover Descovy and Prezcobix–the two drugs taken by John Doe Five, who is a member of the Lowe's Plan. EOR 166–69, 173–74.

The only Employer-Appellee that submitted its procedure for amending its Plan was Time Warner, but Time Warner submitted no evidence that it ever actually amended its Plan to include the Program. EOR 164–66. Thus, there was no evidence in the record that any Employer-Appellee validly amended its Plan to include the Program. In any event, it would have been beyond the scope of a motion to dismiss to do so, which was the basis for Appellants' initial objection.

The ability to obtain medications from Network Pharmacies was part of the Appellants' plans as they alleged, and the discussion of the evidence referenced during the hearing on the motion to dismiss confirmed. EOR 161–74. Without any valid amendment to the Plans, Appellants and all others similarly situated are *still* entitled to the same benefit, which was denied to them through

implementation of the Program. Especially in light of the Court's duty to read the Plaintiffs' allegations in the light most favorable to them on a motion to dismiss, the district court's dismissal of Count V should be reversed.

VI. The Court Erred in Dismissing Appellants' UCL Claim Because It Properly Alleged Independent Unlawful and Unfair Business Acts and Practices

Finally, Appellants properly asserted a UCL claim. As a claim for violation of any of the above federal statutes would also be a predicate for establishing an unlawful business practice under the UCL, if the Court reverses any of the causes of action discussed above it must also reverse dismissal of the UCL claim. *Levitt v. Yelp! Inc.*, 765 F.3d 1123, 1130 (9th Cir. 2014) ("In prohibiting 'any unlawful' business practice, the UCL 'borrows violations of other laws and treats them as unlawful practices that the unfair competition law makes independently actionable.'").

In addition, the district court dismissed independent aspects of the UCL claim. One was related to violations of 45 C.F.R. § 156.122(e) and California's constitutional right of privacy, and the other related to the "unfair" prong of the UCL. As set forth in detail above, the Complaint at ¶¶ 115, 122, 186 specifically alleged how this federal regulation was violated for at least some of the plans and enrollees. EOR 75, 77, 92. The district court ruled those allegations did not exist, with no explanation. EOR 201–202. While the district court recognized the privacy

violation allegations, the district court stated, without the benefit of any discovery, these were only "isolated incident[s]" and thus would not justify a UCL claim. EOR 201. Yet the UCL was amended in 1992 to make clear even single acts can support a UCL violation, and if permitted Appellants could amend to allege additional incidents. *Stop Youth Addiction v. Lucky Stores, Inc.*, 17 Cal. 4th 553, 570 (1998).

As to the separate "unfairness" prong of the UCL, the district court recognized there are various tests for determining if a practice is unfair. None are properly resolved on a motion to dismiss. *McKell v. Wash. Mut., Inc.*, 142 Cal. App. 4th 1457, 1473 (2006). As explained above, the business practice at issue here was not entering into or challenging the terms of a contract between CVS Caremark and pharmacies or between CVS Caremark and the Employer-Appellees, as Appellants have no control over such contracts. What made the business practice at issue "unfair" was how the Program was actually applied, resulting in conduct that violated public policy and harmed consumers. EOR 93, ¶ 189. Resolution of that issue requires a review of evidence from both sides and is independent of any contractual relationship between the parties. The district court's sole focus on irrelevant UCL rulings arising out of contract cases was thus not a proper basis for dismissing this claim. EOR 200. Such rulings further constitute reversible error.

CONCLUSION

This Court should reverse the decision of the district court and remand for proceedings consistent with this Court's decision.

DATED: June 6, 2019

Respectfully submitted,

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Dated: June 6, 2019

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CERTIFICATE OF SERVICE

In compliance with Fed. R. App. P. 25 and 6th Cir. R. 25, I hereby certify that on this 6th day of June, 2019, I electronically filed the foregoing with the Clerk of the court for the United States Court of Appeals for the Sixth Circuit using the appellate CM/ECF system. I certify that I am a registered CM/ECF user and that all parties have registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Alan M. Mansfield
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ADDENDA

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ADDENDUM A

(3) *FEHBP plan*. Any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by aggregate enrollment that is offered to all health-benefits-eligible federal employees under 5 USC 8903.

(4) *HMO*. The coverage plan with the largest insured commercial non-Medicaid enrollment offered by a health maintenance organization operating in the State.

(b) *EHB-benchmark selection standards*. In order to become an EHB-benchmark plan as defined in §156.20 of this subchapter, a state-selected base-benchmark plan must meet the requirements for coverage of benefits and limits described in §156.110 of this subpart; and

(c) *Default base-benchmark plan*. If a State does not make a selection using the process described in this section, the default base-benchmark plan will be the largest plan by enrollment in the largest product by enrollment in the State's small group market.

(d) *Applicability date:* For plan years beginning on or after January 1, 2020, §156.111 applies in place of this section.

[78 FR 12866, Feb. 25, 2013, as amended at 80 FR 10871, Feb. 27, 2015; 83 FR 17068, Apr. 17, 2018]

§156.105 Determination of EHB for multi-state plans.

A multi-state plan must meet benchmark standards set by the U.S. Office of Personnel Management.

§156.110 EHB-benchmark plan standards.

An EHB-benchmark plan must meet the following standards:

(a) *EHB coverage*. Provide coverage of at least the following categories of benefits:

(1) Ambulatory patient services.

(2) Emergency services.

(3) Hospitalization.

(4) Maternity and newborn care.

(5) Mental health and substance use disorder services, including behavioral health treatment.

(6) Prescription drugs.

(7) Rehabilitative and habilitative services and devices.

(8) Laboratory services.

(9) Preventive and wellness services and chronic disease management.

(10) Pediatric services, including oral and vision care.

(b) *Coverage in each benefit category*. A base-benchmark plan not providing any coverage in one or more of the categories described in paragraph (a) of this section, must be supplemented as follows:

(1) *General supplementation methodology*. A base-benchmark plan that does not include items or services within one or more of the categories described in paragraph (a) of this section must be supplemented by the addition of the entire category of such benefits offered under any other benchmark plan option described in §156.100(a) of this subpart unless otherwise described in this subsection.

(2) *Supplementing pediatric oral services*. A base-benchmark plan lacking the category of pediatric oral services must be supplemented by the addition of the entire category of pediatric oral benefits from one of the following:

(i) The FEDVIP dental plan with the largest national enrollment that is described in and offered to federal employees under 5 U.S.C. 8952; or

(ii) The benefits available under that State's separate CHIP plan, if a separate CHIP plan exists, to the eligibility group with the highest enrollment.

(3) *Supplementing pediatric vision services*. A base-benchmark plan lacking the category of pediatric vision services must be supplemented by the addition of the entire category of pediatric vision benefits from one of the following:

(i) The FEDVIP vision plan with the largest national enrollment that is offered to federal employees under 5 USC 8982; or

(ii) The benefits available under the State's separate CHIP plan, if a separate CHIP plan exists, to the eligibility group with the highest enrollment.

(c) *Supplementing the default base-benchmark plan*. A default base-benchmark plan as defined in §156.100(c) of this subpart that lacks any categories of essential health benefits will be supplemented by HHS in the following order, to the extent that any of the plans offer benefits in the missing EHB category:

(1) The largest plan by enrollment in the second largest product by enrollment in the State's small group market, as defined in §155.20 of this subchapter (except for pediatric oral and vision benefits);

(2) The largest plan by enrollment in the third largest product by enrollment in the State's small group market, as defined in §155.20 of this subchapter (except for pediatric oral and vision benefits);

(3) The largest national FEHBP plan by enrollment across States that is offered to federal employees under 5 USC 8903 (except for pediatric oral and vision benefits);

(4) The plan described in paragraph (b)(2)(i) of this section for pediatric oral care benefits; and

(5) The plan described in paragraph (b)(3)(i) of this section for pediatric vision care benefits.

(d) *Non-discrimination.* Not include discriminatory benefit designs that contravene the non-discrimination standards defined in §156.125 of this subpart.

(e) *Balance.* Ensure an appropriate balance among the EHB categories to ensure that benefits are not unduly weighted toward any category.

(f) *Determining habilitative services.* If the base-benchmark plan does not include coverage for habilitative services, the State may determine which services are included in that category.

[78 FR 12866, Feb. 25, 2013, as amended at 80 FR 10871, Feb. 27, 2015]

§156.111 State selection of EHB-benchmark plan for plan years beginning on or after January 1, 2020.

(a) Subject to paragraphs (b), (c), (d) and (e) of this section, for plan years beginning on or after January 1, 2020, a State may change its EHB-benchmark plan by:

(1) Selecting the EHB-benchmark plan that another State used for the 2017 plan year under §§156.100 and 156.110;

(2) Replacing one or more categories of EHBs established at §156.110(a) in the State's EHB-benchmark plan used for the 2017 plan year with the same category or categories of EHB from the EHB-benchmark plan that another State used for the 2017 plan year under §§156.100 and 156.110; or

(3) Otherwise selecting a set of benefits that would become the State's EHB-benchmark plan.

(b) A State's EHB-benchmark plan must:

(1) *EHB coverage.* Provide coverage of items and services for at least the categories of benefits at §156.110(a), including an appropriate balance of coverage for these categories of benefits.

(2) *Scope of benefits.* (i) Provide a scope of benefits equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at §156.110(a), the scope of benefits provided under a typical employer plan, defined as either:

(A) One of the selecting State's 10 base-benchmark plan options established at §156.100, and available for the selecting State's selection for the 2017 plan year; or

(B) The largest health insurance plan by enrollment within one of the five largest large group health insurance products by enrollment in the State, as product and plan are defined at §144.103 of this subchapter, provided that:

(*1*) The product has at least 10 percent of the total enrollment of the five largest large group health insurance products in the State;

(*2*) The plan provides minimum value, as defined under §156.145;

(*3*) The benefits are not excepted benefits, as established under §146.145(b), and §148.220 of this subchapter; and

(*4*) The benefits in the plan are from a plan year beginning after December 31, 2013.

(ii) Not exceed the generosity of the most generous among a set of comparison plans, including:

(A) The State's EHB-benchmark plan used for the 2017 plan year, and

(B) Any of the State's base-benchmark plan options for the 2017 plan year described in §156.100(a)(1), supplemented as necessary under §156.110.

(iii) Not have benefits unduly weighted towards any of the categories of benefits at §156.110(a);

(iv) Provide benefits for diverse segments of the population, including women, children, persons with disabilities, and other groups; and

ADDENDUM B

§ 156.122 Prescription drug benefits.

(a) A health plan does not provide essential health benefits unless it:

(1) Subject to the exception in paragraph (b) of this section, covers at least the greater of:

(i) One drug in every United States Pharmacopeia (USP) category and class; or

(ii) The same number of prescription drugs in each category and class as the EHB-benchmark plan;

(2) Submits its formulary drug list to the Exchange, the State or OPM; and

(3) For plans years beginning on or after January 1, 2017, uses a pharmacy and therapeutics (P&T) committee that meets the following standards.

(i) *Membership standards.* The P&T committee must:

(A) Have members that represent a sufficient number of clinical specialties to adequately meet the needs of enrollees.

(B) Consist of a majority of individuals who are practicing physicians, practicing pharmacists and other practicing health care professionals who are licensed to prescribe drugs.

(C) Prohibit any member with a conflict of interest with respect to the issuer or a pharmaceutical manufacturer from voting on any matters for which the conflict exists.

(D) Require at least 20 percent of its membership to have no conflict of interest with respect to the issuer and any pharmaceutical manufacturer.

(ii) *Meeting standards.* The P&T committee must:

(A) Meet at least quarterly.

(B) Maintain written documentation of the rationale for all decisions regarding formulary drug list development or revision.

(iii) *Formulary drug list establishment and management.* The P&T committee must:

(A) Develop and document procedures to ensure appropriate drug review and inclusion.

(B) Base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

(C) Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs.

(D) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange.

(E) Evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually.

(F) Review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered drug.

(G) Review new FDA-approved drugs and new uses for existing drugs.

(H) Ensure the issuer's formulary drug list:

(*1*) Covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states, and does not discourage enrollment by any group of enrollees; and

(*2*) Provides appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

(b) A health plan does not fail to provide EHB prescription drug benefits solely because it does not offer drugs approved by the Food and Drug Administration as a service described in § 156.280(d) of this subchapter.

(c) A health plan providing essential health benefits must have the following processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan (a request for exception). In the event that an exception request is granted, the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing under § 156.130 and when calculating the plan's actuarial value under § 156.135.

(1) *Standard exception request.* For plans years beginning on or after January 1, 2016:

(i) A health plan must have a process for an enrollee, the enrollee's designee,

or the enrollee's prescribing physician (or other prescriber) to request a standard review of a decision that a drug is not covered by the plan.

(ii) A health plan must make its determination on a standard exception and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following receipt of the request.

(iii) A health plan that grants a standard exception request must provide coverage of the non-formulary drug for the duration of the prescription, including refills.

(2) *Expedited exception request.* (i) A health plan must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request an expedited review based on exigent circumstances.

(ii) Exigent circumstances exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug.

(iii) A health plan must make its coverage determination on an expedited review request based on exigent circumstances and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 24 hours following receipt of the request.

(iv) A health plan that grants an exception based on exigent circumstances must provide coverage of the non-formulary drug for the duration of the exigency.

(3) *External exception request review.* For plans years beginning on or after January 1, 2016:

(i) If the health plan denies a request for a standard exception under paragraph (c)(1) of this section or for an expedited exception under paragraph (c)(2) of this section, the health plan must have a process for the enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request that the original exception request and subsequent denial of such request be reviewed by an independent review organization.

(ii) A health plan must make its determination on the external exception request and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following its receipt of the request, if the original request was a standard exception request under paragraph (c)(1) of this section, and no later than 24 hours following its receipt of the request, if the original request was an expedited exception request under paragraph (c)(2) of this section.

(iii) If a health plan grants an external exception review of a standard exception request, the health plan must provide coverage of the non-formulary drug for the duration of the prescription. If a health plan grants an external exception review of an expedited exception request, the health plan must provide coverage of the non-formulary drug for the duration of the exigency.

(4) *Application of coverage appeals laws.* (i) A State may determine that a health plan in the State satisfies the requirements of this paragraph (c) if the health plan has a process to allow an enrollee to request and gain access to clinically appropriate drugs not otherwise covered by the health plan that is compliant with the State's applicable coverage appeals laws and regulations that are at least as stringent as the requirements of this paragraph (c) and include:

(A) An internal review;

(B) An external review;

(C) The ability to expedite the reviews; and

(D) Timeframes that are the same or shorter than the timeframes under paragraphs (c)(1)(ii), (c)(2)(iii), and (c)(3)(ii) of this section.

(ii) [Reserved]

(d)(1) For plan years beginning on or after January 1, 2016, a health plan must publish an up-to-date, accurate, and complete list of all covered drugs on its formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to plan

enrollees, prospective enrollees, the State, the Exchange, HHS, the U.S. Office of Personnel Management, and the general public. A formulary drug list is easily accessible when:

(i) It can be viewed on the plan's public Web site through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number; and

(ii) If an issuer offers more than one plan, when an individual can easily discern which formulary drug list applies to which plan.

(2) A QHP in the Federally-facilitated Exchange must make available the information described in paragraph (d)(1) of this section on its Web site in an HHS-specified format and also submit this information to HHS, in a format and at times determined by HHS.

(e) For plan years beginning on or after January 1, 2017, a health plan providing essential health benefits must have the following access procedures:

(1) A health plan must allow enrollees to access prescription drug benefits at in-network retail pharmacies, unless:

(i) The drug is subject to restricted distribution by the U.S. Food and Drug Administration; or

(ii) The drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.

(2) A health plan may charge enrollees a different cost-sharing amount for obtaining a covered drug at a retail pharmacy, but all cost sharing will count towards the plan's annual limitation on cost sharing under §156.130 and must be accounted for in the plan's actuarial value calculated under §156.135.

[78 FR 12866, Feb. 25, 2013, as amended at 79 FR 30350, May 27, 2014; 80 FR 10871, Feb. 27, 2015; 81 FR 12349, Mar. 8, 2016; 81 FR 53032, Aug. 11, 2016]

§156.125 Prohibition on discrimination.

(a) An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

(b) An issuer providing EHB must comply with the requirements of §156.200(e) of this subchapter; and

(c) Nothing in this section shall be construed to prevent an issuer from appropriately utilizing reasonable medical management techniques.

§156.130 Cost-sharing requirements.

(a) *Annual limitation on cost sharing.* (1) For a plan year beginning in the calendar year 2014, cost sharing may not exceed the following:

(i) For self-only coverage—the annual dollar limit as described in section 223(c)(2)(A)(ii)(I) of the Internal Revenue Code of 1986 as amended, for self-only coverage that that is in effect for 2014; or

(ii) For other than self-only coverage—the annual dollar limit in section 223(c)(2)(A)(ii)(II) of the Internal Revenue Code of 1986 as amended, for non-self-only coverage that is in effect for 2014.

(2) For a plan year beginning in a calendar year after 2014, cost sharing may not exceed the following:

(i) For self-only coverage—the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage, as defined in paragraph (e) of this section.

(ii) For other than self-only coverage—twice the dollar limit for self-only coverage described in paragraph (a)(2)(i) of this section.

(b) [Reserved]

(c) *Special rule for network plans.* In the case of a plan using a network of providers, cost sharing paid by, or on behalf of, an enrollee for benefits provided outside of such network is not required to count toward the annual limitation on cost sharing (as defined in paragraph (a) of this section).

(d) *Increase annual dollar limits in multiples of 50.* For a plan year beginning in a calendar year after 2014, any increase in the annual dollar limits described in paragraph (a) of this section that does not result in a multiple of 50 dollars will be rounded down, to the next lowest multiple of 50 dollars.

(e) *Premium adjustment percentage.* The premium adjustment percentage is

ADDENDUM C

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Part II

Department of Health and Human Services

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Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; Final Rule

general public. Issuers must also include accurate information on any restrictions on the manner in which the drug can be obtained in the formulary drug list, including prior authorization, step therapy, quantity limits, and any access restrictions related to obtaining the drug from a brick and mortar retail pharmacy, such as only being accessible through a mail-order pharmacy because the drug requires special handling. The formulary drug list must be up-to-date, which means that the formulary drug list must accurately list all of the health plan's covered drugs at that time. To meet this requirement, we would expect that the issuer would make any coverage changes simultaneously with updating the formulary drug list and therefore, if an issuer makes a change to its formulary, it would not implement the change until the issuer has posted the change to the formulary drug list on its Web site. We understand that our standard for updating the formulary drug list is stricter than is the case for the typical private market plan, but we believe that the value of increased transparency to consumers is critically important to ensuring that consumers are making informed decisions about their health care. Issuers are prohibited from limiting the updates to their formulary drug list to only formulary changes that negatively impact enrollees, such as removal of drugs from the formulary drug list. Also, the URL that takes a consumer to the issuer's formulary drug list on its Web site must be the same direct formulary drug list URL link for obtaining information on prescription drug coverage in the SBC, in accordance with § 147.200(a)(2)(i)(K), and for QHPs on the Exchanges, this link must be the same link displayed to prospective enrollees on the applicable Exchange Web site. As discussed in the preamble to § 156.250, in addition to the requirements imposed by § 156.250, QHP issuers may also have duties to make this information accessible to individuals with disabilities and individuals with LEP under Federal civil rights laws that also might apply, including section 1557 of the Affordable Care Act, section 504 of the Rehabilitation Act of 1973, and Title VI of the Civil Rights Act. For the FFEs, this URL must be the one that issuers provide through the QHP application for display on HealthCare.gov. While these regulations do not prohibit issuers from providing their drug lists in a searchable or dynamic format on their Web sites, consumers should not have to create an account, be an enrollee in the plan, or navigate multiple Web pages to view the formulary drug list. Specifically, the link needs to be the direct link to the formulary drug list. Further, if an issuer has multiple formulary drug lists, consumers should be able to easily discern which formulary drug list applies to which plan. Also, the Web page should clearly list which plans the formulary drug list applies to using the marketing name for the plan, which for Marketplace plans would be the marketing name used on HealthCare.gov. The revised § 156.122(d) is effective beginning with the 2016 plan year, and we expect that most issuers already have a formulary drug list available via a URL link and will only need to make certain minor modifications to its link to be in compliance with the new § 156.122(d)(1).

Comment: Several commenters supported the proposal for issuers to make the formulary drug list information available in a machine-readable file or a format specified by HHS, stating that this would improve transparency and foster development of additional tools to help consumers make informed decisions about their coverage. Commenters recommended types of information that should be included and the development of tools similar to tools developed by the Medicare Part D program. Others supported allowing various options on how to search for covered drugs, such as by the drug name or listing alphabetically. Conversely, some commenters opposed the proposal, expressing concerns about data integrity, accuracy, confidentiality, and managing third parties' use of this data. Some commenters were concerned that the machine-readable data collection would be duplicative, and noted that implementing any standard would be time-consuming and requested the opportunity to provide additional stakeholder feedback. Some commenters suggested use of an application programming interface (API) to support making formulary drug list information more transparent.

Response: We believe a machine-readable file or a format specified by HHS will increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand plans' formulary drug lists. Based on the comments received asking us to make formulary drug list information more transparent and accessible to consumers, HHS is finalizing this rule by adding § 156.122(d)(2) to require QHPs in the FFEs to make available the information on the formulary drug list on its Web site in a HHS specified format and also submit this information to HHS, in a format and at times determined by HHS. We agree with commenters that creating a vehicle for consumers to easily determine which plans cover which drugs will help consumers select QHPs that best meet their needs. We recognize that this will require issuer resources, and will provide further details about the specific data elements, frequency of updates, file types, and other crucial information in future guidance.

iv. Section 156.122(e)

Under § 156.122(e), we proposed to require that enrollees be provided with the option to access their prescription drug benefit through retail (brick-and-mortar or non-mail order) pharmacies. This requirement would mean that a health plan that is required to cover the EHB package cannot have a mail-order only prescription drug benefit. This proposed requirement would still allow a health plan to charge a different cost-sharing amount when an enrollee obtains a drug at an in-network retail pharmacy than he or she would pay for obtaining the same covered drug at a mail-order pharmacy. However, as a part of these requirements, we proposed to clarify that this additional cost sharing for the covered drug would count towards the plan's annual limitation on cost sharing under § 156.130 and would need to be taken into account when calculating the actuarial value of the health plan under § 156.135. Additionally, under this proposed policy, issuers would still retain the flexibility to charge a lower cost-sharing amount when obtaining the drug at an in-network retail pharmacy. While this proposal requires coverage of a drug at an in-network retail pharmacy, for plans that do not have a network, the enrollee would be able to go to any pharmacy to access their prescription drug benefit and those plans would, therefore, be in compliance with this proposed standard.

As part of this proposed policy, we proposed that the health plan may restrict access to a particular drug when: (1) The FDA has restricted distribution of the drug to certain facilities or practitioners (including physicians); or (2) appropriate dispensing of the drug requires special handling, provider coordination, or patient education that cannot be met by a retail pharmacy. If the health plan finds it necessary to restrict access to a drug for either of the two reasons listed above, we proposed that it must indicate this restricted access on the formulary drug list under § 156.122(d). We are finalizing these policies as proposed with a technical edit to § 156.122(e)(2) to replace

''higher'' cost sharing with ''different'' cost sharing.

Comment: Several commenters supported proposed § 156.122(e) as helping to ensure that plans do not discourage enrollment by, and thus discriminate against, transient individuals and individuals who have conditions that they wish to keep confidential and discussed other cases in which obtaining a prescription from a mail-order pharmacy is difficult for an enrollee, such as cases where an enrollee with a serious health condition may be unable to wait for the prescription to be filled via a mail-order pharmacy. Other commenters opposed these requirements, stating that it would be costly, limit consumer choice of plans that use mail-order benefits, be contrary to specialty drug market practices, not account for the quality standards used by specialty pharmacies, be contrary to precedent from other Federal programs, and be duplicative. Some commenters were concerned that the issue is outside the scope of EHB, is not reflective of a typical employer plan, does not take into account existing privacy laws, and should require additional rulemaking that, for instance, takes into account the NAIC's pending model act on network adequacy. Other commenters wanted clarification that preventive services drugs must be covered at no cost sharing at retail pharmacies, and other commenters discussed similar and overlapping State requirements. Several commenters wanted additional exceptions, such as an exclusion related to specialty drugs and pharmacies, and some commenters supported implementing this provision in 2016 while others supported a 2017 implementation date.

Response: The intention of § 156.122(e) is to ensure all enrollees in plans required to cover EHB are able to use the prescription drug benefit if needed, and is intended to expand options for these enrollees. Thus, the purpose of this policy is not to limit the ability of issuers to use mail-order pharmacies—issuers can continue to influence consumer choice through cost sharing. The issuers need only provide enrollees with the option to access drugs that are not exempted under § 156.122(e)(1)(i) and (ii) at an in-network retail pharmacy. There are instances in which obtaining a drug through a mail-order pharmacy may not be a viable option, such as when an individual does not have a stable living environment and does not have a permanent address, or when a retail pharmacy option better ensures that consumers can access their EHB prescription drug benefit on short notice. In such cases, we do not believe that making drugs available only by mail order constitutes fulfilling the obligation under section 1302(b)(1)(F) of the Affordable Care Act to provide prescription drug coverage as part of EHB. We also believe that making drugs available only by mail order could discourage enrollment by, and thus discriminate against, transient individuals and individuals who have conditions that they wish to keep confidential. We also believe that this provision is important to ensure uniformity in benefit design and consumer choice. Therefore, we are finalizing § 156.122(e) as proposed and with a clarification that this policy will be effective beginning with the 2017 plan year.

Issuers retain the ability to charge different cost sharing for drugs obtained at a retail pharmacy, but for non-grandfathered health plans in the individual and small group markets that must provide coverage of the essential health benefit package under section 1302(a) of the Affordable Care Act, all cost sharing, including any difference between the cost sharing for mail order and the cost sharing for retail, must count towards the plan's annual limitation on cost sharing in accordance with § 156.130(a) and must be taken into account when calculating the actuarial value of the health plan in accordance with § 156.135. We are clarifying that these issuers can apply higher or lower cost sharing, that is, nothing requires an issuer to use higher cost sharing for drugs obtained from a retail pharmacy. As a result, some or all of the costs associated with this option may be passed on to the consumer who chooses to use it. However, nothing in this provision supersedes State law that may apply other cost sharing standards to mail-order pharmacies. For plans that do not have a network, enrollees should be able to go to any pharmacy to access their prescription drug benefit, and those plans would, therefore, be in compliance with this standard. In addition, this requirement is not intended to disrupt or supersede the rules regarding cost sharing for preventive service benefits when such coverage includes drugs.

In response to comments, we considered an exceptions process under which an enrollee could make a request to obtain the prescription at a brick and mortar retail pharmacy. However, we are concerned that if we allow an exception process, the issuer would retain the option to deny the request, and such a process could be seen as burdensome on the enrollee. In particular, an exception process could be burdensome for enrollees with complex health conditions if they had to seek an exception request for each of their prescription drugs that they take.

We understand that specialty pharmacies provide more integrated services, aimed at improving clinical outcomes while limiting costs relating to the delivery and management of the product, than a typical mail-order pharmacy or a brick and mortar retail pharmacy. We understand that drugs on the specialty tier of a formulary are not necessarily the same drugs that a specialty pharmacy would provide. Our intention with this policy was not to disrupt the specialty pharmacy market, and we understand that exceptions will be needed for many drugs that are only accessible via a specialty pharmacy. For these reasons, we are finalizing the exceptions that allow a health plan to restrict access to certain drugs in limited circumstances. As part of this requirement, a health plan may restrict access to mail order, which may include specialty pharmacies, for a particular drug when: (1) The FDA has restricted distribution of the drug to certain facilities or practitioners (including physicians); or (2) appropriate dispensing of the drug requires special handling, provider coordination, or patient education that cannot be met by a retail pharmacy. For instance, certain drugs have a Risk Evaluation and Mitigation Strategy (REMS) that includes Elements to Assure Safe Use that may require that pharmacies, practitioners, or health care settings that dispense the drug be specially certified and that may limit access to the drugs to certain health care settings.[52] If the health plan finds it necessary to restrict access to a drug for either of the reasons listed above, it must indicate this restricted access on the formulary drug list that plans must make publicly available under § 156.122(d). The provisions at § 156.122(e)(1)(i) and (ii) allow an issuer to restrict access to certain drugs at a retail pharmacy for the specific reasons noted in those paragraphs. Although issuers may subject these drugs to reasonable utilization management techniques, the fact that these drugs have restricted access should not in and of itself be a justification for applying these techniques to these drugs.

Issuers must implement the revised § 156.122(e) no later than for the start of

[52] FDA requires a Risk Evaluation and Mitigation Strategies (REMS) for certain drugs to ensure that the benefits of a drug or biological product outweigh its risks. The following is FDA's list of currently approved REMS at: *http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111350.htm.*

the 2017 plan year, and we have added this clarification to the regulation.

v. Other Comments on the Preamble to § 156.122

In addition to the proposed provisions above, we urged issuers to temporarily cover non-formulary drugs (including drugs that are on an issuer's formulary but require prior authorization or step therapy) as if they were on formulary (or without imposing prior authorization or step therapy requirements) during the first 30 days of coverage. We encouraged plans to adopt this policy to accommodate the immediate needs of enrollees, while allowing the enrollee sufficient time to go through the prior authorization or drug exception processes.

Comment: Some commenters sought clarification about coverage of medical drugs and preventive service drugs. Others recommended requiring limits to formulary changes during the plan year. Several commenters recommended that we require issuers to temporarily cover non-formulary drugs during the first 30 days of coverage or longer and other commenters were against this policy, stating that it is not a typical requirement in the private market, and that it is costly and counterintuitive to formulary transparency. Other commenters supported transition policies, but acknowledged the importance of flexibility for issuers in developing these policies.

Response: Preventive services, including preventive service drugs, are required to be covered as part of EHB. Non-grandfathered group health plans and health insurance coverage must provide benefits for preventive health services, including preventive service drugs, without cost sharing, consistent with the requirements of section 2713. Similarly, the rules set forth under § 156.122 are specific to coverage of drugs under the prescription drug EHB category. Issuers could cover drugs administered as part of another service (such as during an inpatient hospitalization or a physician service) under the EHB category that covers that service, in addition to covering the drug under the prescription drug EHB category. We believe this clarification reflects the current practice of issuers.

We are also concerned about issuers making mid-year formulary changes, especially changes that negatively affect enrollees. We are monitoring this issue to consider whether further standards are needed. We also note that, under guaranteed renewability requirements and the definitions of ''product'' and ''plan,'' issuers generally may not make plan design changes, including changes to drug formularies, other than at the time of plan renewal. We recognize that certain mid-year changes to drug formularies related to the availability of drugs in the market may be necessary and appropriate.

We are not requiring coverage of a transitional fill at this time. As stated in the proposed rule, we will consider whether additional requirements may be needed in this area. We remain concerned that new enrollees may be unfamiliar with what is covered on their new plan's formulary drug list and the process and procedures under the plan. Further, some new enrollees whose drugs are covered by the plan's formulary may need to obtain prior authorization or go through step therapy to have coverage for their drugs, and others may need time to work with their provider to determine which formulary drug the individual should be transitioned to. For these reasons, we urge issuers to temporarily fill drugs that are not on the formulary (or are on an issuer's formulary but require prior authorization or step therapy) as if they were on formulary (or without imposing prior authorization or step therapy requirements) during the first 30 days of coverage. We encourage plans to adopt this policy to accommodate the immediate needs of enrollees, while allowing the enrollee sufficient time to go through the prior authorization or drug exception processes.

Comment: Some commenters recommended that we implement the prescription benefit requirements in 2017 or later. Others recommended that all of the prescription drug benefit changes be implemented in 2016. Some had separate recommendations for the timing or only commented on the timing for certain requirements.

Response: We recognize that certain prescription benefit changes under § 156.122 will be easier to implement than others. For that reason, we are finalizing our proposal effective dates for § 156.122(c) and new § 156.122(d), such that they are effective for plan years beginning or after January 1, 2016. These requirements are typical of the current market and would require updating and modifying of systems and procedures to align with the finalized policy. We are finalizing our proposed effective dates for the revisions to § 156.122(a) and new § 156.122(e) such that they are effective for plan years beginning on or after January 1, 2017 to better ensure a smooth transition in implementing these policies.

e. Prohibition on Discrimination (§ 156.125)

Section 1302(b)(4) of the Affordable Care Act directs the Secretary to address certain standards in defining EHB, including elements related to balance, discrimination, the needs of diverse sections of the population, and denial of benefits. We have interpreted this provision, in part, as a prohibition on discrimination by issuers providing EHB. Under § 156.125, which implements the prohibition on discrimination provisions, an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

As described in the proposed rule, since we finalized § 156.125, we have become aware of benefit designs that we believe would discourage enrollment by individuals based on age or based on health conditions, in effect making those plan designs discriminatory, thus violating this prohibition. Some issuers have maintained limits and exclusions that were included in the State EHB benchmark plan. As we have previously stated in guidance, EHB-benchmark plans may not reflect all requirements effective for plan years starting on or after January 1, 2014. Therefore, when designing plans that are substantially equal to the EHB-benchmark plan, issuers should design plan benefits, including coverage and limitations, to comply with requirements and limitations that apply to plans beginning in 2014.[53]

In the proposed rule, we discussed three examples of potentially discriminatory practices: (1) Attempts to circumvent coverage of medically necessary benefits by labeling the benefit as a ''pediatric service,'' thereby excluding adults; (2) refusal to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen, absent an appropriate reason for such refusal; and (3) placing most or all drugs that treat a specific condition on the highest cost tiers.

In this final rule, CMS adopts the same approach as described in the proposed rule. As we indicated in the proposed rule and the 2014 Letter to Issuers, we will notify an issuer when we see an indication of a reduction in the generosity of a benefit in some

[53] Guide to Reviewing EHB Benchmark Plans—*http://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html#review* benchmarks.

ADDENDUM D

positive steps it has taken in the past to improve respect for human rights and civil liberties. On a recent trip to North Africa, Secretary Clinton was complimentary of Morocco's efforts to reach a peaceful solution in Western Sahara. But the Saharawi people, including Aminatou Haidar, have passionately advocated for the right to self-determination, and the international community, including the U.N., has long supported a referendum on self-determination, which has thus far been blocked by the Moroccan Government.

I have no opinion on what the political status of Western Sahara should be, but I am disappointed that the Moroccan authorities have acted in this way because it only adds to the mistrust and further exacerbates a conflict that has proven hard enough to resolve. Nothing positive will be achieved by denying the basic rights of someone of Ms. Haidar's character and reputation, or restricting the right to travel of other residents of Western Sahara, as the Moroccan authorities have increasingly done in the last 2 months.

In the past, the United States has opposed proposals to extend the U.N.'s mandate in Western Sahara, currently limited to peacekeeping, to human rights monitoring. The recent crackdown on Ms. Haidar and other Saharawis who continue to insist on a referendum on self-determination suggests that human rights monitoring is needed and should be seriously considered when the U.N. mission comes up for renewal in April. I encourage the Department of State to review this question and to consult with the Congress about it.

I am confident that our relations with Morocco, already strong, will continue to deepen in the future. We share many important interests. But the United States was also instrumental in the creation of the Universal Declaration of Human Rights, and while we sometimes fall short ourselves, we will continue to strive to defend those whose fundamental rights are denied, wherever it occurs.

I appreciate the efforts the Department of State has made to try to help resolve this situation. I urge the Moroccan Government to reconsider its decision to deport Ms. Haidar, which will not advance its interests in the conflict over Western Sahara. It should return her passport, readmit her, and let her return to her home and family.

60TH ANNIVERSARY OF THE VOICE OF AMERICA'S UKRAINIAN SERVICE

Mr. CARDIN. Mr. President, for six decades the Voice of America's, VOA, Ukrainian-language service has been providing an invaluable service through its consistent broadcasting of factual and comprehensive news and information to the people of Ukraine.

During the first four decades of its existence, the Ukrainian service reached a Ukrainian population starving for information under an extremely strictly controlled, propagandistic Soviet media environment. Ukrainians went to great lengths and some risks to overcome Soviet censorship, which included the jamming of VOA and other shortwave international broadcasting.

During the Cold War VOA Ukrainian provided its listeners with uncensored news about such monumental events as the Hungarian Revolution, the Prague Spring, rise of Solidarity, and the fall of the Berlin Wall. A variety of shows worked to open the outside world to Ukrainian listeners, including a Popular Music Show, a Youth Show, and the long running series Democracy in Action, which was about how democracy works in the United States.

The Ukrainian service also focused on developments within Ukraine itself. VOA broadcasts about Soviet human rights violations in Ukraine, including its coverage of activities of the Helsinki process and the Helsinki Commission, gave sustenance to Helsinki Monitors and other Ukrainian human rights activists, especially those languishing in the gulag for daring to call upon the Soviet government to live up to its Helsinki Final Act obligations. They knew that they were not forgotten. Furthermore, the Ukrainian service also provided objective information about the Chornobyl nuclear disaster and the development of Ukraine's movement for democracy and independence, culminating in the December 1, 1991, referendum in Ukraine in which an overwhelming majority of Ukrainians voted for the restoration of their nation's independence.

For nearly two decades since, VOA's Ukrainian service has continued to fill an important role in Ukraine's evolving democracy. VOA reported on the challenges that Ukraine faced and on the U.S.'s considerable support and assistance for Ukraine, including in the dismantling of the nuclear arsenal it inherited from the Soviet Union. During the Orange Revolution, VOA Ukrainian helped to reassure millions of Ukrainians that the international community would not sanction electoral fraud.

As Ukraine has evolved, so has the Ukrainian Service. While no longer broadcasting on radio as it did for most of its 60 years, it reaches more Ukrainians than ever with daily broadcasts over Ukrainian television—something unthinkable during Soviet rule—and reporting on its website. It continues to report on what is happening in Ukraine, but also it continues to cover every aspect of American life and society. As Chairman of the Helsinki Commission, I commend the ongoing role of VOA's Ukrainian service in helping Ukraine fulfill its aspirations in becoming a more fully democratic, independent, and secure.

WORLD AIDS DAY

Mr. CARDIN. Mr. President, I rise today in recognition of World AIDS Day, an international commemoration held each year on December 1 to raise awareness of HIV and AIDS around the world. The theme for this year's World AIDS Day is ''universal access and human rights.''

Around the world, 33 million people were living with HIV in 2007, including 2.7 million new infections. In the U.S., more than 1.2 million people are infected with HIV. According to the Joint United Nations Program on HIV/AIDS, or UNAIDS, global reports indicated that 2 million people died from AIDS-related causes in 2007.

Globally, sub-Saharan Africa is the hardest-hit region when it comes to HIV infection, accounting for two-thirds of all people living with HIV and for three-quarters of AIDS deaths in 2007. Sadly, 75 percent of young people worldwide who are diagnosed with HIV are girls living in sub-Saharan Africa.

According to the results of a global youth survey conducted in 99 countries, 50 percent of young people have a dangerously low knowledge of how the disease is contracted and can be prevented. Another report by UNAIDS collected data from 64 countries and found that fewer than 40 percent of young people have basic information about HIV. This knowledge gap is particularly disturbing when taking into account a UNICEF report that indicates that 4.9 million young people, ages 15–24, are living with HIV worldwide.

Despite these statistics, recent advances in prevention and treatment of HIV give hope for the future. Globally, approximately 38 percent of the 730,000 children under 15 who needed antiretroviral drugs to treat HIV in 2008 were receiving the necessary therapy, according to UNAIDS. This is a huge increase from just a little over 10 percent in 2005.

The percentage of pregnant women living with HIV who received antiretroviral treatment to prevent mother-to-child transmission has increased from 9 percent in 2004 to 33 percent in 2007.

Despite recent improvements in treatment coverage and declining mother-to-child transmission of HIV, problems remain in preventing and treating the disease. In addition, the number of new HIV infections continues to outpace the advances made in treatment numbers for every two people put on antiretroviral drugs, another five become newly infected with the disease. Clearly, prevention measures are essential to continue the fight against HIV/AIDS.

No State in the U.S. is immune from the effects of HIV/AIDS, and the epidemic is deeply felt among Marylanders as well. At the end of 2007, Maryland had 28,270 people living with HIV and AIDS. That same year, Maryland ranked fourth in the U.S. for the number of AIDS cases per 100,000 people.

The Maryland Department of Health and Mental Hygiene has estimated that

there are between 6,000 and 9,000 Marylanders who are unaware that they are infected with HIV. Of the 1.2 million people in the United States who are estimated to be infected with HIV, as many as 21 percent are unaware that they have the virus.

To address this problem, it is crucial that HIV screening be readily available and accessible to everyone at little or no cost. This will increase the rate of diagnosis in individuals that have HIV and will accelerate their treatment.

The Patient Protection and Affordable Care Act will address this need and will help achieve the goals outlined by the theme of this year's World AIDS Day campaign of ''universal access and human rights.''

First and foremost, the bill eliminates discrimination based on pre-existing conditions. Individuals with HIV will no longer be rejected from insurance coverage because of their disease.

The bill also encourages outreach to enroll vulnerable and underserved populations in Medicare and CHIP, including adults and children with HIV/AIDS. It provides personal responsibility education grants to States to create HIV/AIDS education programs for adolescents.

The bill will also cover preventive services recommended by the U.S. Preventive Services Task Force, including HIV testing for all pregnant women. This testing will be provided at no individual cost, making it universally accessible to all women in the U.S. Testing pregnant women for HIV is vital for prevention efforts, allowing women who test positive to begin antiretroviral drugs to prevent transmission to their baby.

Furthermore, the Mikulski amendment, which I have cosponsored, would allow coverage for HIV testing for all women, regardless of risk, based on expert recommendations from the Health Resources and Services Administration.

The Patient Protection and Affordable Care Act also provides grants to encourage training health care workers to treat individuals with HIV/AIDS and other vulnerable populations.

Because of the numerous provisions in the bill that will help the prevention and treatment of HIV/AIDS, several groups have expressed their support for the Patient Protection and Affordable Care Act. Among the groups that I have heard from is the HIV Medicine Association, an organization representing 3,600 physicians, scientists, and health care professionals who work on the frontlines of the HIV/AIDS epidemic in communities across the country.

We must continue to fight HIV/AIDS, and I urge my colleagues to support the measures outlined in the Patient Protection and Affordable Care Act that will further our efforts to combat this disease.

RECOGNIZING REAL SALT LAKE SOCCER TEAM

Mr. HATCH. Mr. President, I rise and offer my congratulations to the Real Salt Lake soccer team, the newly crowned champions of Major League Soccer. While Utah has a number of sports teams with proud traditions—both collegiate and professional—Real Salt Lake has brought to my home State its first major professional championship since 1971, when the Utah Stars won the ABA title. Fans throughout Utah are thrilled.

Real Salt Lake came to Utah in 2004 and faced difficulties during its first three seasons. In just its fourth season, however, Real Salt Lake made an improbable run to the Western Conference Finals, despite only sneaking into the playoffs on the last day of the regular season. They eventually lost that game by a score of 1–0, but with their first playoff appearance, and opening their new world class soccer-specific stadium, their future was filled with promising signs.

In 2009 Real Salt Lake delivered on that promise. Once again, it was the last team to qualify for the playoffs and was the lowest overall seed. Despite barely squeaking into the playoffs, this team of overachievers sure made some noise once they got there. They quickly reeled off a string of consecutive upsets against glitzier opponents with established stars, dispatching top-seeded and defending MLS champion Columbus and then powerhouse Chicago and its star Cuauhtemoc Blanco.

On November 22, the title game in Seattle pitted the little-known upstarts of Real Salt Lake against the Western Conference champions, the Los Angeles Galaxy and its mega-stars Landon Donovan and David Beckham. After 90 minutes of regulation play and 30 minutes of overtime, the game remained tied at 1–1. In the penalty kick shootout, Real Salt Lake emerged victorious 5–4 as Donovan's potential game-tying spot kick sailed harmlessly over the crossbar. Real Salt Lake had delivered the first championship of its kind in Utah in nearly four decades—and it couldn't have come in a more exciting fashion or to a more deserving group of athletes.

In the end, it wasn't the Galaxy of stars that prevailed; it was Real Salt Lake with its philosophy that mirrors the words emblazoned on the sign in its home locker room: ''THE TEAM IS THE STAR.'' That teamwork was certainly on display in the title tilt against Los Angeles. It was reflected in Real Salt Lake Robbie Findley's breakout 64th-minute strike that knotted the score at 1–1 and made the team's overtime and penalty kick heroics possible. It was reflected in the play of Salt Lake goalkeeper and Cup final MVP Nick Rimando, who turned away penalties from L.A.'s Jovan Kirovski and Edson Buddle before besting Donovan. Finally, RSL's determination to overcome the odds also mirrors that of its owner, Dave Checketts, coach Jason Kreis and general manager Garth Lagerwey—all of whom turned the team into a champion despite the naysayers who said it couldn't be done.

No, Real Salt Lake's roster did not have the league's biggest stars. But in the words of midfielder Clint Mathis, better known as Cletus, RSL was ''the better team in every game.'' As much as anything else, that explains why champion Real Salt Lake is now the brightest light in MSL's firmament.

Once again, I congratulate Real Salt Lake on this accomplishment. Senator BENNETT and I have introduced a resolution expressing the Senate's congratulations for Real Salt Lake and I urge my colleagues to offer their support.

Mr. BENNETT. Mr. President, I wish to commend and congratulate Real Salt Lake for winning the 2009 Major League Soccer Cup. I am delighted to do so, and feel it is a privilege to honor the MLS Cup champions on the Senate floor. The story of Real Salt Lake is more than just a story about a soccer team capturing the MLS title; it is a story about banding together to overcome obstacles and defying the odds after being counted out and dismissed by ''the experts.'' In many ways, the story of Real Salt Lake is part and parcel of the American experience.

On November 22, 2009, in Seattle, WA, Real Salt Lake, or RSL, faced off against the better-known and widely acclaimed L.A. Galaxy. Just to give a sense of what RSL was up against, listed on the roster for the Galaxy were U.S. National Team star Landon Donovan, and the internationally acclaimed, indeed iconic, David Beckham. The RSL roster, on the other hand, didn't include what's known as a ''designated player,'' or in other words, a recognized superstar. If that wasn't enough, the Galaxy entered the postseason riding high, having finished at the top of the Western Conference in the regular season with a 12–6–12 record, and were expected by most to perform well if not to win the championship. RSL had a far different experience during their regular season, finishing with an 11–12–7 record. Indeed, they barely managed to make it into the eight team playoff that would determine the MLS Cup Champion.

Considering these facts, it would have been easy for RSL to give up. But that wasn't their attitude. When asked about not having a star player, instead of bemoaning that fact, the team's captain, Kyle Beckerman, said, ''We've really bought into the 'star is the team' here in Salt Lake. When we work as a team and [are] doing well it's because everybody's playing well. It pays off.'' This team unity had initially paid off in the postseason for RSL as they defeated the defending champion Columbus Crew, and beat the Chicago Fire in the Eastern Conference finals. Despite this, many doubted whether they could win against the Galaxy in the championship game. When asked

ADDENDUM E

Whitfield
Wilson (SC)
Wittman
Wolf
Young (AK)
Young (FL)

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). There are 2 minutes remaining in this vote.

□ 1829

So the resolution was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

RECOGNIZING MILITARY AVIATORS WHO ESCAPED CAPTURE

The SPEAKER pro tempore. The unfinished business is the vote on the motion to suspend the rules and agree to the resolution, H. Res. 925, as amended, on which the yeas and nays were ordered.

The Clerk read the title of the resolution.

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from Guam (Ms. BORDALLO) that the House suspend the rules and agree to the resolution, H. Res. 925, as amended.

This will be a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 426, nays 0, not voting 4, as follows:

[Roll No. 164]

YEAS—426

Ackerman
Aderholt
Adler (NJ)
Akin
Alexander
Altmire
Andrews
Arcuri
Austria
Baca
Bachmann
Bachus
Baird
Baldwin
Barrett (SC)
Barrow
Bartlett
Barton (TX)
Bean
Becerra
Berkley
Berman
Berry
Biggert
Bilbray
Bilirakis
Bishop (GA)
Bishop (NY)
Bishop (UT)
Blackburn
Blumenauer
Blunt
Boccieri
Bonner
Bono Mack
Boozman
Boren
Boswell
Boucher
Boustany
Boyd
Brady (PA)
Brady (TX)
Braley (IA)
Bright
Broun (GA)
Brown (SC)
Brown, Corrine
Brown-Waite, Ginny
Buchanan
Burgess
Burton (IN)
Butterfield
Buyer
Calvert
Camp
Campbell
Cantor
Cao
Capito
Capps
Capuano
Cardoza
Carnahan
Carney
Carson (IN)
Carter
Cassidy
Castle
Castor (FL)
Chaffetz
Chandler
Childers
Chu
Clarke
Clay
Cleaver
Clyburn
Coble
Coffman (CO)
Cohen
Cole
Conaway
Connolly (VA)
Conyers
Cooper
Costa
Costello
Courtney
Crenshaw
Crowley
Cuellar
Culberson
Cummings
Dahlkemper
Davis (AL)
Davis (CA)
Davis (IL)
Davis (KY)
Davis (TN)
Deal (GA)
DeFazio
DeGette
Delahunt
DeLauro
Dent
Diaz-Balart, L.
Diaz-Balart, M.
Dicks
Dingell
Doggett
Donnelly (IN)
Doyle
Dreier
Driehaus
Duncan
Edwards (MD)
Edwards (TX)
Ehlers
Ellison
Ellsworth
Emerson
Engel
Eshoo
Etheridge
Fallin
Farr
Fattah
Filner
Flake
Fleming
Forbes
Fortenberry
Foster
Frank (MA)
Franks (AZ)
Frelinghuysen
Fudge
Gallegly
Garamendi
Garrett (NJ)
Gerlach
Giffords
Gingrey (GA)
Gohmert
Gonzalez
Goodlatte
Gordon (TN)
Granger
Graves
Grayson
Green, Al
Green, Gene
Griffith
Grijalva
Guthrie
Gutierrez
Hall (NY)
Hall (TX)
Halvorson
Hare
Harman
Harper
Hastings (FL)
Hastings (WA)
Heinrich
Heller
Hensarling
Herger
Herseth Sandlin
Higgins
Hill
Himes
Hinchey
Hinojosa
Hirono
Hodes
Hoekstra
Holden
Holt
Honda
Hoyer
Hunter
Inglis
Inslee
Israel
Issa
Jackson (IL)
Jackson Lee (TX)
Jenkins
Johnson (GA)
Johnson (IL)
Johnson, E. B.
Johnson, Sam
Jones
Jordan (OH)
Kagen
Kanjorski
Kaptur
Kennedy
Kildee
Kilroy
Kind
King (IA)
King (NY)
Kingston
Kirk
Kirkpatrick (AZ)
Kissell
Klein (FL)
Kline (MN)
Kosmas
Kratovil
Kucinich
Lamborn
Lance
Langevin
Larsen (WA)
Larson (CT)
Latham
LaTourette
Latta
Lee (CA)
Lee (NY)
Levin
Lewis (CA)
Lewis (GA)
Linder
Lipinski
LoBiondo
Loebsack
Lofgren, Zoe
Lowey
Lucas
Luetkemeyer
Luján
Lummis
Lungren, Daniel E.
Lynch
Mack
Maffei
Maloney
Manzullo
Marchant
Markey (CO)
Markey (MA)
Marshall
Matheson
Matsui
McCarthy (CA)
McCarthy (NY)
McCaul
McClintock
McCollum
McCotter
McDermott
McGovern
McHenry
McIntyre
McKeon
McMahon
McMorris Rodgers
McNerney
Meek (FL)
Meeks (NY)
Melancon
Mica
Michaud
Miller (FL)
Miller (MI)
Miller (NC)
Miller, Gary
Miller, George
Minnick
Mitchell
Mollohan
Moore (KS)
Moore (WI)
Moran (KS)
Moran (VA)
Murphy (CT)
Murphy (NY)
Murphy, Patrick
Murphy, Tim
Myrick
Nadler (NY)
Napolitano
Neal (MA)
Neugebauer
Nunes
Nye
Oberstar
Obey
Olson
Olver
Ortiz
Owens
Pallone
Pascrell
Pastor (AZ)
Paul
Paulsen
Payne
Pence
Perlmutter
Perriello
Peters
Peterson
Petri
Pingree (ME)
Pitts
Platts
Poe (TX)
Polis (CO)
Pomeroy
Posey
Price (GA)
Price (NC)
Putnam
Quigley
Radanovich
Rahall
Rangel
Rehberg
Reichert
Reyes
Richardson
Rodriguez
Roe (TN)
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rohrabacher
Rooney
Ros-Lehtinen
Roskam
Ross
Rothman (NJ)
Roybal-Allard
Royce
Ruppersberger
Rush
Ryan (OH)
Ryan (WI)
Salazar
Sánchez, Linda T.
Sanchez, Loretta
Sarbanes
Scalise
Schakowsky
Schauer
Schiff
Schmidt
Schock
Schrader
Schwartz
Scott (GA)
Scott (VA)
Sensenbrenner
Serrano
Sessions
Sestak
Shadegg
Shea-Porter
Sherman
Shimkus
Shuler
Shuster
Simpson
Sires
Skelton
Slaughter
Smith (NE)
Smith (NJ)
Smith (WA)
Snyder
Souder
Space
Speier
Spratt
Stark
Stearns
Stupak
Sullivan
Sutton
Tanner
Taylor
Teague
Terry
Thompson (CA)
Thompson (MS)
Thompson (PA)
Thornberry
Tiahrt
Tiberi
Tierney
Titus
Tonko
Towns
Tsongas
Turner
Upton
Van Hollen
Velázquez
Visclosky
Walden
Walz
Wamp
Wasserman Schultz
Waters
Watson
Watt
Waxman
Weiner
Welch
Westmoreland
Whitfield
Wilson (OH)
Wilson (SC)
Wittman
Wolf
Woolsey
Wu
Yarmuth
Young (AK)
Young (FL)

NOT VOTING—4

Boehner
Foxx
Kilpatrick (MI)
Smith (TX)

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (Ms. EDWARDS of Maryland) (during the vote). Two minutes remain in the vote.

□ 1841

So (two-thirds being in the affirmative) the rules were suspended and the resolution, as amended, was agreed to.

The result of the vote was announced as above recorded.

The title of the resolution was amended so as to read: ''Expressing the sense of the House of Representatives regarding the meritorious service performed by aviators in the United States Armed Forces who, as a result of hostile action, mechanical failures, or other problems, were forced to evade or escape enemy capture, were captured but subsequently escaped, or were compelled to endure arduous confinement, retaliation, and even death as a result of their efforts to evade capture or escape.''.

A motion to reconsider was laid on the table.

SENATE AMENDMENTS TO H.R. 3590, SERVICE MEMBERS HOME OWNERSHIP TAX ACT OF 2009, AND H.R. 4872, HEALTH CARE AND EDUCATION RECONCILIATION ACT OF 2010

The SPEAKER pro tempore. Pursuant to House Resolution 1203, it is now in order to debate the topics addressed by the Senate amendments to the bill (H.R. 3590) to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes, and the topics addressed by the bill (H.R. 4872) to provide for reconciliation pursuant to section 202 of the concurrent resolution on the budget for fiscal year 2010.

The gentleman from Maryland (Mr. HOYER) and the gentleman from Ohio (Mr. BOEHNER), or their designees, each will control 60 minutes.

The Chair recognizes the gentleman from California (Mr. WAXMAN) for 15 minutes as a designee of the majority leader.

GENERAL LEAVE

Mr. WAXMAN. I would like to ask unanimous consent that all Members have 5 days in which to revise and extend their remarks and insert extraneous material in the RECORD.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. WAXMAN. Madam Speaker, I yield 1 minute to the majority leader of the House of Representatives, the gentleman from Maryland (Mr. HOYER).

Mr. HOYER. I thank my friend for yielding.

Today is March 21, 2010. On March 21, 1965, Martin Luther King, Jr., led a march across the Edmund Pettus Bridge. It was a march across that bridge for the vote in this democracy.

It was a march towards a greater freedom for many Americans. It was a march for a better quality of life for many Americans. Indeed, it was a march across the Edmund Pettus Bridge for freedom and a better realization of the promise of our democracy.

Today, March 21, 2010, we will cross another bridge. It is not a physical bridge, but it is a bridge that too many Americans find that they cannot cross; a river that separates them from the security of having available the best health care that is available in the world available to them.

We are here to conclude a day of debate, which concludes months of debate, in a national conversation that began more than a century ago.

□ 1845

But this much is beyond debate. American health care is on an unsustainable course. By the end of this debate, another family will have fallen into bankruptcy because someone had the bad fortune simply to be sick. More families will have joined them in paying more and more for less and less health coverage. More businesses will have weighted bankruptcy against cutting their workers' care and their workers will have lost.

We have before us a bill to change an unsustainable course. That is our choice this evening. It is a historic choice. It's a choice that all of us volunteered to be put in the position to make. It is a choice that we will be honored to make this evening. We stood in this Chamber tonight with JOHN DINGELL, JOHN DINGELL, who stood at that rostrum with the gavel that the Speaker will use tonight to gavel through Medicare, that ensured that millions and millions and millions of seniors would not be crushed by poverty and put into bankruptcy by the cost of health care.

Indeed, they will have been given the opportunity for a longer, better quality of life in America when JOHN DINGELL brought that gavel down on that desk and noted the passage of Medicare in 1965.

For more than 3,000 district events, more than 100 hearings, and almost 2 years of public debate, health insurance reform has stood up to the scrutiny, to criticism, indeed, to falsehoods. But this purpose is older than that. Before we were born, the task of bringing affordable health care to every American was on our Nation's agenda, waiting for this day. At the beginning of this decade in 2002, George W. Bush said, ''All Americans should be able to choose a health care plan that meets their needs at affordable prices.'' George Bush was right.

In 1976, Gerald Ford spoke of ''our effort to upgrade and perpetuate our total health care system so no individual in this country will lack help whenever or wherever he needs it.'' Gerald Ford was right.

And Richard Nixon said this, ''Let us act now.'' That was in 1974, when there were far fewer Americans who did not have health insurance and where health care was less costly. Richard Nixon was right in 1974 on this issue. Let us in 2010, in a bipartisan way, perhaps not a bipartisan vote, but recognizing that this has been a bipartisan objective, a bipartisan vision, for those Republican Presidents and Democratic Presidents whom I have not quoted but whom, as all of you know, were equally committed to that vision and that objective, affordable health care for all, for all Americans. It was embraced by both parties' nominees in the last campaign, Senator Obama and Senator MCCAIN.

But what a campaign of fear this bill has faced this last year. Its critics call it, without justification, and we will hear it tonight, a ''government takeover.'' That's not true, but if you believe it's true, perhaps you think we ought to repeal veterans health care, which is clearly government-run health care. Perhaps we ought to repeal Medicare, government participated but private sector providers. Perhaps you believe Medicare should be repealed. I don't think you do; I hope you don't.

It is more control, however, for whom? For consumers, and less for insurance companies. It is the end of discrimination against Americans with preexisting conditions, and the end of medical bankruptcy and caps on benefits. It is coverage you can rely on whether you lose your job or become your own boss, coverage that reaches 95 percent of all Americans. Its critics call it tyranny. There is none.

It is a free, competitive, transparent marketplace where individuals and small businesses can pool together to buy private insurance at low rates. It is lower cost for the middle class and an end to the prescription drug doughnut hole that has faced too many struggling seniors. Its critics mock this as ''out-of-control government.''

In truth, it is the biggest definite-reduction bill any of us will have an opportunity to vote on in this Congress and, indeed, in other Congresses as well. Indeed, it's the deepest definite reduction since the Clinton budget of the 1990s that ushered in a budget surplus and historic prosperity.

According to the nonpartisan CBO, this bill is $143 billion in savings in the first decade and more than $1 trillion of savings in the second decade. We can add to those deficit savings real cost controls that bring down the price of the world's most expensive health care. Take those into account, says leading health care economist David Cutler, and America saves an additional $600 billion in the first 10 years and even more in the second 10 years.

Yet there are some who hope for the bill's defeat. They would see that, I think, as the defeat of one party. One Senator made that observation and said this might be the President's Waterloo. If this bill fails, the Waterloo will be that of the people who are without health care insurance, the people who are struggling to make sure that their children are healthy and well and safe. But it would be a defeat for them and for our country, for a healthy America is a stronger America.

They saw the same thing in 1993, my Republican colleagues, when to a person, as I believe will happen tonight, unfortunately, in 1993, to a person they did the same thing. My Republican friends voted without a single exception against the 1993 economic reform plan of the Clinton administration.

Congressman BOEHNER asked, ''Who does this spending stimulate except maybe the liberal faculty at Harvard or Berkeley?''

Congressman Kasich said, ''If it was to work, then I'd have to become a Democrat. ''

It did work, and he didn't change. It was a partisan vote, Mr. Speaker, a partisan vote that helped create 22.7 million new jobs, contrary to what so many of my Republican friends said that bill would do, and a record budget surplus of $5.6 trillion, contrary to the assertion of Mr. Armey that it would create deep debt.

That bill passed through a gauntlet of slurs, hyperbole, and untruths, and so did Medicare, which Republicans called ''brazen socialism,'' and so did Social Security, which a Republican Congressman called the ''lash of the dictator.''

I don't know whether there are any Republicans in this body tonight that believe that Social Security is the lash of the dictator. I hope not.

Those slurs were false in 1935, they were false in 1965, and, ladies and gentlemen of this House, they are false in 2010. Ladies and gentlemen of this House, this bill, this bill will stand in the same company, for the misguided outrage of its opposition and for its lasting accomplishment of the American people.

In closing, Mr. Speaker, I want to honor some of the ''little punk staffers'' who gave so much to help us bring this bill to the floor. I say to my friends on the other side of the aisle who did so much to bring your prescription drug bill to the floor, they need to be honored. They need to be thanked. They need to be respected for the work they do for this House, for each of us but, more importantly, for America.

From the Legislative Counsel's Office, Ed Grossman, Jessica Shapiro, Megan Renfrew, Warren Burke, Larry Johnston, Henry Christrup, Wade Ballou and Scott Probst.

I also want to honor, Mr. Speaker, the tireless staffs of the House Committees on Ways and Means, Energy and Commerce, Education and Labor, Rules, and the Budget, as well as the staff of the CBO, Doug Elmendorf, Holly Harvey, Phil Ellis, Kate Massey, Pete Fontaine and the whole CBO health care team, along with Tom Barthold, and everyone of the staff on the Joint Committee on Taxation, who contributed to their estimates.

ADDENDUM F

Federal Register
Vol. 80, No. 149
Tuesday, August 4, 2015

Presidential Documents

Title 3—

The President

Executive Order 13703 of July 30, 2015

Implementing the National HIV/AIDS Strategy for the United States for 2015–2020

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to ensure improved health outcomes for Americans at risk for or living with HIV/AIDS and achieve greater coordination across the Federal Government, I hereby order as follows:

Section 1. *Policy.* My Administration has made substantial progress in addressing the domestic HIV epidemic since the National HIV/AIDS Strategy for the United States (Strategy), the first of its kind, was released in July 2010. The Strategy has served as a blueprint for executive departments and agencies (agencies) as well as for community partners in the private and nonprofit sectors. This effort has led to increased coordination and collaboration among agencies and fostered the use of evidence-based policy approaches for improving HIV prevention and care.

Federal, State, and local agencies have contributed to significant improvements in health outcomes through their enhanced focus on the HIV care continuum—the sequential stages of care from being diagnosed to achieving viral suppression. Our partners across all levels of government and all sectors of society have also worked to ensure that all Americans living with HIV/AIDS receive our full support at every stage of their illness.

Further, my Administration has been committed to reducing the HIV-related disparities experienced by certain populations, including gay and bisexual men of all races and ethnicities, Black women and men, Latino women and men, people who inject drugs, youth aged 13–24, people in the Southern United States, and transgender women. Addressing the intersection between HIV/AIDS, violence against women and girls, and gender-related health disparities has also been a priority. The Working Group on the Intersection of HIV/AIDS, Violence Against Women and Girls, and Gender-related Health Disparities established in my memorandum of March 30, 2012, has focused its efforts on increasing screenings for HIV and intimate partner violence, addressing violence and trauma when supporting women in HIV care, and expanding public education efforts across all levels of government regarding HIV and violence against women and girls.

Today, I am releasing the National HIV/AIDS Strategy for the United States: Updated to 2020 (Updated Strategy) to build on this progress. The Updated Strategy integrates the recommendations of the HIV Care Continuum Working Group, established in Executive Order 13649 of July 15, 2013 (HIV Care Continuum Initiative), and the recommendations of the Working Group on the Intersection of HIV/AIDS, Violence Against Women and Girls, and Gender-related Health Disparities, so that their work can inform the Nation's response to the domestic HIV/AIDS epidemic. The Updated Strategy also takes into account recent research advancements in our understanding of HIV/AIDS, and builds on the historic successes of the Affordable Care Act, which is helping millions of Americans, including those who are living with HIV, access affordable, quality health care.

This order is designed to ensure successful implementation of the Updated Strategy by requiring coordination and collaboration by, and accountability of, the Federal Government; fostering enhanced and innovative partnerships with State, tribal, and local governments; and encouraging the commitment

of all parts of society. The duties and authorities this order assigns are in addition to those assigned by my memorandum of July 13, 2010 (Implementation of the National HIV/AIDS Strategy). In light of recent progress and continuing challenges, we must continue to improve our national effort to reduce new HIV infections, increase access to care for people living with HIV, reduce HIV-related disparities and health inequities, and achieve greater coordination across all levels of government.

Sec. 2. *Role of the White House Office of National AIDS Policy (ONAP).* (a) The Director of ONAP, in consultation with the Director of the Office of Management and Budget (OMB), shall be responsible for monitoring the implementation of the Updated Strategy.

(b) The Director of ONAP shall annually report to the President on the implementation of the Updated Strategy, including progress in meeting key targets and taking key actions identified in the Updated Strategy and the Federal Action Plan, an annual guidepost developed by ONAP in conjunction with agencies, designed to implement new efforts to address the domestic HIV/AIDS epidemic.

Sec. 3. *Lead Agency Responsibilities.* While the Updated Strategy will require a Government-wide effort in order to succeed fully, certain agencies have primary responsibilities and competencies in implementing the Updated Strategy.

(a) *Designation of Lead Agencies.* Lead agencies for implementing the Updated Strategy shall be:

(i) the Department of Defense;

(ii) the Department of Justice;

(iii) the Department of the Interior;

(iv) the Department of Labor;

(v) the Department of Health and Human Services;

(vi) the Department of Housing and Urban Development;

(vii) the Department of Education;

(viii) the Department of Veterans Affairs;

(ix) the Department of Homeland Security; and

(x) the Social Security Administration.

(b) *Lead Agency Action Plans.* Within 100 days of the date of this order, the head of each lead agency shall submit a report to ONAP and OMB on the agency's action plan for implementing the Updated Strategy. The plans shall assign responsibilities to agency officials, designate reporting structures for actions identified in the Federal Action Plan, and identify other appropriate actions to advance the Updated Strategy. The plans shall also include steps to strengthen coordination in planning, budgeting for, and evaluating domestic HIV/AIDS programs within and across agencies. Lead agencies are encouraged to consider, and reflect in their plans, steps to streamline grantee reporting requirements and funding announcements related to HIV/AIDS programs and activities.

(c) *Ongoing Responsibilities of Lead Agencies.* The head of each lead agency shall:

(i) designate an official responsible for coordinating the agency's ongoing efforts to implement the Updated Strategy;

(ii) develop and support a process for sharing progress reports, including status updates on achieving specific quantitative targets established by the Updated Strategy, with relevant agencies and ONAP on an annual basis, or at such other times as ONAP requests; and

(iii) in consultation with OMB, use the budget development process to prioritize programs and activities most critical to meeting the goals of the Updated Strategy.

Sec. 4. *Other Agency Responsibilities.* All agencies that support HIV/AIDS programs and activities shall ensure that, to the extent permitted by law, they are meeting the goals of the Updated Strategy.

(a) *Department of State.* Within 100 days of the date of this order, the Secretary of State shall submit to ONAP and OMB recommendations for improving the Government-wide response to the domestic HIV/AIDS epidemic, based on lessons learned in implementing the President's Emergency Plan for AIDS Relief program.

(b) *Equal Employment Opportunity Commission (Commission).* Within 100 days of the date of this order, the Chair of the Commission shall submit to ONAP and OMB recommendations for increasing employment opportunities for people living with HIV and a plan for addressing employment-related discrimination against people living with HIV, consistent with the Commission's authorities and other applicable law.

Sec. 5. *Role of the Presidential Advisory Council on HIV/AIDS (PACHA).* The PACHA, which was established by Executive Order 12963 of June 14, 1995 (Presidential Advisory Council on HIV/AIDS), as amended, shall monitor the implementation of the Updated Strategy and make recommendations to the Secretary of Health and Human Services (Secretary) and to the Director of ONAP, as appropriate, concerning implementation and progress in achieving the Updated Strategy's goals.

Sec. 6. *National HIV/AIDS Strategy Federal Interagency Working Group.* There is established the National HIV/AIDS Strategy Federal Interagency Working Group (Federal Interagency Working Group) to support the implementation of the Updated Strategy.

(a) *Membership.* The Federal Interagency Working Group shall be co-chaired by the Director of ONAP and the Secretary or their designees. In addition to the Co-Chairs, the Federal Interagency Working Group shall consist of representatives from each lead agency, OMB, and any other agency or office designated by the Co-Chairs.

(b) *Consultation.* The Federal Interagency Working Group shall consult with the PACHA, as appropriate.

(c) *Outreach.* The Federal Interagency Working Group shall hold regular meetings and conduct outreach with representatives of private and nonprofit organizations, State, tribal, and local governments and agencies, elected officials, and other interested persons to assist the Federal Interagency Working Group in its efforts.

(d) *Functions.* As part of its efforts, the Federal Interagency Working Group shall:

(i) request and review information from agencies describing their efforts to implement the Updated Strategy;

(ii) share and disseminate best practices to combat the HIV epidemic among agencies and other stakeholders;

(iii) integrate new HIV-related research results into the overall implementation of the Updated Strategy;

(iv) obtain input from community partners, scientific and technical experts, and stakeholders in State, tribal, and local governments to inform implementation of the Updated Strategy;

(v) increase government and public awareness of HIV-related issues;

(vi) specify how to better align and coordinate Federal efforts, both within and across agencies, to improve health outcomes for Americans at risk for or living with HIV; and

(vii) integrate the Working Group on the Intersection of HIV/AIDS, Violence Against Women and Girls, and Gender-related Health Disparities into the implementation of the Updated Strategy.

(e) *Reporting.*

(i) Within 100 days of the date of this order, the Federal Interagency Working Group shall provide recommendations to the President on actions that agencies should take to implement the Updated Strategy through 2020.

(ii) The Director of ONAP shall include, as part of the Director's annual report to the President, a report prepared by the Federal Interagency Working Group concerning Government-wide progress in implementing the Updated Strategy.

Sec. 7. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department, agency, or the head thereof; or

(ii) the functions of the Director of OMB relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

THE WHITE HOUSE,
July 30, 2015.

[FR Doc. 2015–19209
Filed 8–3–15; 8:45 am]
Billing code 3295–F5

ADDENDUM G

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Part IV

Department of Health and Human Services

Office of the Secretary

45 CFR Part 92

Nondiscrimination in Health Programs and Activities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 92

RIN 0945–AA02

Nondiscrimination in Health Programs and Activities

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: This final rule implements Section 1557 of the Affordable Care Act (ACA) (Section 1557). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. The final rule clarifies and codifies existing nondiscrimination requirements and sets forth new standards to implement Section 1557, particularly with respect to the prohibition of discrimination on the basis of sex in health programs other than those provided by educational institutions and the prohibition of various forms of discrimination in health programs administered by the Department of Health and Human Services (HHS or the Department) and entities established under Title I of the ACA. In addition, the Secretary is authorized to prescribe the Department's governance, conduct, and performance of its business, including, here, how HHS will apply the standards of Section 1557 to HHS-administered health programs and activities.

DATES: *Effective Date:* This rule is effective July 18, 2016.

Applicability Dates: The provisions of this rule are generally applicable on the date the rule is effective, except to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Eileen Hanrahan at (800) 368–1019 or (800) 537–7697 (TDD).

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys),* a service of the U.S. Government Printing Office. This database can be accessed via the Internet at *http://www.gpo.gov/fdsys.*

I. Background

Section 1557 of the ACA provides that an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d *et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. 1681 *et seq.* (sex), the Age Discrimination Act of 1975 (Age Act), 42 U.S.C. 6101 *et seq.* (age), or Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794 (disability), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the Act or its amendments. Section 1557 states that the enforcement mechanisms provided for and available under Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of addressing violations of Section 1557.

Section 1557(c) of the ACA authorizes the Secretary of the Department to promulgate regulations to implement the nondiscrimination requirements of Section 1557. In addition, the Secretary is authorized to prescribe regulations for the Department's governance, conduct, and performance of its business, including how HHS applies the standards of Section 1557 to HHS-administered health programs and activities.[1]

A. Regulatory History

On August 1, 2013, the Office for Civil Rights of the Department (OCR) published a Request for Information (RFI) in the **Federal Register** to solicit information on issues arising under Section 1557. OCR received 402 comments; one-quarter (99) were from organizational commenters, with the remainder from individuals.

On September 8, 2015, OCR issued a proposed rule, ''Nondiscrimination in Health Programs and Activities,'' in the **Federal Register**, and invited comment on the proposed rule by all interested parties.[2] The comment period ended on November 9, 2015. In total, we received approximately 24,875 comments on the proposed rule. Comments came from a wide variety of stakeholders, including, but not limited to: Civil rights/advocacy groups, including language access organizations, disability rights organizations, women's organizations, and organizations serving lesbian, gay, bisexual, or transgender (LGBT) individuals; health care providers; consumer groups; religious organizations; academic and research institutions; reproductive health organizations; health plan organizations; health insurance issuers; State and local agencies; and tribal organizations. Of the total comments, 23,344 comments were from individuals. The great majority of those comments were letters from individuals that were part of mass mail campaigns organized by civil rights/advocacy groups.

B. Overview of the Final Rule

This final rule adopts the same structure and framework as the proposed rule: Subpart A sets forth the rule's general provisions; Subpart B contains the rule's nondiscrimination provisions; Subpart C describes specific applications of the prohibition on discrimination to health programs and activities; and Subpart D describes the procedures that apply to enforcement of the rule.

OCR has made some changes to the proposed rule's provisions, based on the comments we received. Among the significant changes are the following.

Section 92.4 now provides a definition of the term ''national origin.''

OCR decided against including a blanket religious exemption in the final rule; however, the final rule includes a provision noting that insofar as application of any requirement under the rule would violate applicable Federal statutory protections for religious freedom and conscience, such application would not be required.

OCR has modified the notice requirement in § 92.8 to exclude publications and significant communications that are small in size from the requirement to post all of the content specified in § 92.8; instead, covered entities will be required to post only a shorter nondiscrimination statement in such communications and publications, along with a limited number of taglines. OCR also is translating a sample nondiscrimination statement that covered entities may use in fulfilling this obligation. It will be available by the effective date of this rule.

In addition, with respect to the obligation in § 92.8 to post taglines in at least the top 15 languages spoken nationally by persons with limited English proficiency, OCR has replaced the national threshold with a threshold

[1] 5 U.S.C. 301.

[2] 80 FR 54172 (Sept. 8, 2015).

requiring taglines in at least the top 15 languages spoken by limited English proficient populations statewide.

OCR has changed § 92.101 to provide that sex-specific health programs or activities are allowable only where the covered entity can demonstrate an exceedingly persuasive justification, *i.e.,* that the sex-specific program is substantially related to the achievement of an important health-related or scientific objective.

OCR has changed § 92.201, addressing the obligation to take reasonable steps to provide meaningful access. That section now requires the Director to evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue to the individual with limited English proficiency, and to take into account all other relevant factors, including whether the entity has developed and implemented an effective language access plan, appropriate to its particular circumstances. The final rule deletes the specific list of illustrative factors set out in the proposed rule.

Also, OCR has changed § 92.203, addressing accessibility of buildings and facilities for individuals with disabilities, to require covered entities that were covered by the 2010 Americans with Disabilities Act (ADA) Standards for Accessible Design prior to the effective date of this final rule to comply with those standards for new construction or alterations by the effective date of the final rule. The final rule also narrows § 92.203's safe harbor for building and facility accessibility so that compliance with the Uniform Federal Accessibility Standards (UFAS) will be deemed compliance with this part only if construction or alteration was commenced before the effective date of the final rule and the facility or part of the facility was not covered by standards under the ADA. As nearly all covered entities under the final rule are already covered by the ADA standards, these changes impose a de minimis cost.

Section 92.301 has been changed to clarify that compensatory damages for violations of Section 1557 are available in administrative and judicial actions to the extent they are available under the authorities referenced in Section 1557. Finally, we have added a severability clause to § 92.2, to indicate our intention that the rule be construed to give the maximum effect permitted by law to each provision.

In responding to the comments it received on the proposed rule, OCR has provided a thorough explanation of each of these changes in the preamble. OCR has also clarified some of the nondiscrimination requirements of Section 1557 and made some technical changes to the rule's provisions. In addition, we have added some definitions to proposed § 92.4, as summarized in the preamble to this final rule.

II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments

A. General Comments

OCR received a large number of comments asking that we categorically declare in the final rule that certain actions are or are not discriminatory. For example, some commenters asked that OCR state that a modification to add medically necessary care, or a prohibition on exclusions of medically necessary services, is never a fundamental alteration to a health plan. Similarly, other commenters asked that OCR include a statement in the final rule that an issuer's refusal to cover core services commonly needed by individuals with intellectual disabilities is discrimination on the basis of disability. Still other commenters asked that OCR state that limiting health care and gender transition services to transgender individuals over the age of 18 is discriminatory. Other commenters asked that OCR state that it is discriminatory to require individuals with psychiatric disabilities to see a mental health professional in order to continue receiving treatment for other conditions.

Many of these same commenters asked that OCR supplement the final rule with in-depth explanations and analyses of examples of discrimination. For example, several commenters asked that OCR add an example of discrimination in research trials. Similarly, many other commenters asked that OCR add an example of what they considered to be disability discrimination in health insurance practices, such as higher reimbursement rates for care in segregated settings.

OCR appreciates the commenters' desire for further information on the application of the rule to specific circumstances. OCR's intent in promulgating this rule is to provide consumers and covered entities with a set of standards that will help them understand and comply with the requirements of Section 1557. Covered entities should bear in mind the purposes of the ACA and Section 1557—to expand access to care and coverage and eliminate barriers to access—in interpreting requirements of the final rule. But we neither address every scenario that might arise in the application of these standards nor state that certain practices as a matter of law are ''always'' or ''never'' permissible. The determination of whether a certain practice is discriminatory typically requires a nuanced analysis that is fact-dependent. Nonetheless, OCR has included in the preamble a number of examples of issues and circumstances that may raise compliance concerns under the final rule.

OCR also received several comments, primarily from representatives of the insurance industry, recommending that where specific Centers for Medicare & Medicaid Services (CMS) or State requirements apply to covered entities, OCR should either (1) harmonize all standards with existing CMS rules, or (2) allow issuers to be deemed compliant with Section 1557 if they are compliant with existing Federal or State law. For example, some commenters requested that compliance with CMS regulations that pertain to qualified health plans or insurance benefit design, such as prescription drug formularies designed by a pharmacy and therapeutics committee, be deemed compliance with the final rule on Section 1557. These commenters were concerned that CMS or a State might approve a plan that OCR might later find discriminatory. The commenters sought clarification on how OCR will handle cases involving health plans regulated by multiple authorities, and suggested that a ''deeming'' approach would reduce confusion and avoid duplication of costs and administrative effort. Other commenters asked that compliance with language access standards promulgated by CMS or the States be deemed compliance with the final rule; those comments are discussed in more detail in the preamble at § 92.201.

OCR recognizes the efficiencies inherent in harmonizing regulations to which covered entities are subject under various laws. Indeed, entities covered under Section 1557 are likely also subject to a host of other laws and regulations, including CMS regulations, the Genetic Information Nondiscrimination Act of 2008,[3] the Family and Medical Leave Act, the ADA, Title VII of the Civil Rights Act of 1964, and State laws. OCR will coordinate as appropriate with other Federal agencies to avoid inconsistency and duplication in enforcement efforts.

That said, OCR declines to adopt a deeming approach whereby compliance with another set of laws or regulations automatically constitutes compliance with Section 1557. As to State laws, it

[3] Public Law 110–233, 122 Stat. 881 (2008).

ADDENDUM H

enrollees, prospective enrollees, the State, the Exchange, HHS, the U.S. Office of Personnel Management, and the general public. A formulary drug list is easily accessible when:

(i) It can be viewed on the plan's public Web site through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number; and

(ii) If an issuer offers more than one plan, when an individual can easily discern which formulary drug list applies to which plan.

(2) A QHP in the Federally-facilitated Exchange must make available the information described in paragraph (d)(1) of this section on its Web site in an HHS-specified format and also submit this information to HHS, in a format and at times determined by HHS.

(e) For plan years beginning on or after January 1, 2017, a health plan providing essential health benefits must have the following access procedures:

(1) A health plan must allow enrollees to access prescription drug benefits at in-network retail pharmacies, unless:

(i) The drug is subject to restricted distribution by the U.S. Food and Drug Administration; or

(ii) The drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.

(2) A health plan may charge enrollees a different cost-sharing amount for obtaining a covered drug at a retail pharmacy, but all cost sharing will count towards the plan's annual limitation on cost sharing under §156.130 and must be accounted for in the plan's actuarial value calculated under §156.135.

[78 FR 12866, Feb. 25, 2013, as amended at 79 FR 30350, May 27, 2014; 80 FR 10871, Feb. 27, 2015; 81 FR 12349, Mar. 8, 2016; 81 FR 53032, Aug. 11, 2016]

§156.125 Prohibition on discrimination.

(a) An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

(b) An issuer providing EHB must comply with the requirements of §156.200(e) of this subchapter; and

(c) Nothing in this section shall be construed to prevent an issuer from appropriately utilizing reasonable medical management techniques.

§156.130 Cost-sharing requirements.

(a) *Annual limitation on cost sharing.* (1) For a plan year beginning in the calendar year 2014, cost sharing may not exceed the following:

(i) For self-only coverage—the annual dollar limit as described in section 223(c)(2)(A)(ii)(I) of the Internal Revenue Code of 1986 as amended, for self-only coverage that that is in effect for 2014; or

(ii) For other than self-only coverage—the annual dollar limit in section 223(c)(2)(A)(ii)(II) of the Internal Revenue Code of 1986 as amended, for non-self-only coverage that is in effect for 2014.

(2) For a plan year beginning in a calendar year after 2014, cost sharing may not exceed the following:

(i) For self-only coverage—the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage, as defined in paragraph (e) of this section.

(ii) For other than self-only coverage—twice the dollar limit for self-only coverage described in paragraph (a)(2)(i) of this section.

(b) [Reserved]

(c) *Special rule for network plans.* In the case of a plan using a network of providers, cost sharing paid by, or on behalf of, an enrollee for benefits provided outside of such network is not required to count toward the annual limitation on cost sharing (as defined in paragraph (a) of this section).

(d) *Increase annual dollar limits in multiples of 50.* For a plan year beginning in a calendar year after 2014, any increase in the annual dollar limits described in paragraph (a) of this section that does not result in a multiple of 50 dollars will be rounded down, to the next lowest multiple of 50 dollars.

(e) *Premium adjustment percentage.* The premium adjustment percentage is

ADDENDUM I

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 92

RIN 0945–AA02

Nondiscrimination in Health Programs and Activities

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or ''the Department'') is issuing this proposed rule on Section 1557 of the Affordable Care Act (ACA) (Section 1557). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. Section 1557(c) of the ACA authorizes the Secretary of the Department to promulgate regulations to implement the nondiscrimination requirements of Section 1557. In addition, the Secretary is authorized to prescribe regulations for the Department's governance, conduct, and performance of its business, including, here, how HHS will apply the standards of Section 1557 to HHS-administered health programs and activities.

DATES: Submit comments on or before November 9, 2015.

ADDRESSES: You may submit comments, identified by RIN Number 0945–AA02, by any of the following methods:

- *Federal eRulemaking Portal:* You may submit electronic comments at *http://www.regulations.gov*. Follow the instructions for submitting electronic comments. Attachments should be in Microsoft Word or Excel; however, we prefer Microsoft Word.
- *Regular, Express, or Overnight Mail:* You may mail written comments (one original and two copies) to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: 1557 NPRM (RIN 0945–AA02), Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW., Washington, DC 20201. Mailed comments may be subject to delivery delays due to security procedures. Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.
- *Hand Delivery or Courier:* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to the following address only: Office for Civil Rights, Attention: 1557 NPRM (RIN 0945–AA02), Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW., Washington, DC 20201. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)
- *Inspection of Public Comments:* All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. We will post all comments received before the close of the comment period at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Claudia Adams, at (800) 368–1019 or (800) 537–7697 (TDD).

SUPPLEMENTARY INFORMATION:

I. Background

Section 1557 of the ACA provides that an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d *et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. 1681 *et seq.* (sex), the Age Discrimination Act of 1975 (Age Act), 42 U.S.C. 6101 *et seq.* (age), or Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794 (disability), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any health program or activity, any part of which is receiving Federal financial assistance, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the Act or its amendments. Section 1557 states that the enforcement mechanisms provided for and available under Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of addressing violations of Section 1557. The Department is responsible for developing regulations to implement Section 1557.

On August 1, 2013, the Office for Civil Rights of the Department (OCR) published a Request for Information (RFI) in the **Federal Register** to obtain information that would assist OCR in drafting the proposed regulation.[1] The RFI solicited information on issues arising under Section 1557. OCR received 402 comments. Of the total comments, one-quarter (99) were from organizational commenters, with the remainder from individuals. Of the organizational comments, one-third (33) were from civil rights/advocacy groups with over half of these (17) coming from organizations serving lesbian, gay, bisexual, or transgender (LGBT) individuals. Six comments were received from health care providers (including two local government health agencies) and two were from health insurance providers or provider organizations. Of the comments from individuals, 239 were personal testimonies from transgender individuals describing their experiences of discrimination in the health care setting.

OCR has carefully reviewed all comments received, and has referenced them where appropriate and relevant in this preamble. The proposed rule both clarifies and codifies existing nondiscrimination requirements, and also sets forth new standards to implement Section 1557, particularly with respect to the prohibition of discrimination on the basis of sex in health programs other than those provided by educational institutions and the prohibition of various forms of discrimination in health programs administered by the Department and entities established under Title I of the ACA. The Department invites comment on this proposed rule by all interested parties, including comment from Tribes on application of the rule to them.

Subpart A—General Provisions

Purpose and Effective Date (§ 92.1)

Proposed § 92.1 states that the purpose of this part is to implement Section 1557 of the ACA, which prohibits discrimination in certain health programs and activities on the grounds prohibited under Title VI, Title IX, the Age Act, and Section 504, which together prohibit discrimination on the basis of race, color, national origin, sex, age, or disability.

Section 92.1 also establishes that the effective date of the Section 1557 implementing regulation shall be 60 days after the publication of the final rule in the **Federal Register**.

Application (§ 92.2)

Section 1557 applies to all health programs and activities, any part of which receives Federal financial assistance from any Federal agency. In addition, Section 1557 applies to all programs and activities that are administered by an Executive Agency or any entity established under Title I of the ACA.

[1] 78 FR 46558 (Aug. 1, 2013).

Finally, paragraph (d) of § 92.101 effectuates technical changes to apply the provisions incorporated in § 92.101(b) and (c) to covered entities obligated to comply with this proposed rule by, among other things, replacing references to ''recipient'' in the incorporated provisions with ''covered entity.''

Subpart C—Specific Applications to Health Programs and Activities

Section 1557 is unique among Federal civil rights laws in that it specifically addresses discrimination in health programs and activities. To provide additional specificity regarding nondiscrimination requirements in this setting, Subpart C builds upon pre-existing civil rights regulations referenced in Subpart B. Due to the nature and importance of health care, health-related insurance, and other health-related coverage to individuals and communities, OCR is proposing these additional specific requirements to ensure that covered entities have clear instruction in areas where OCR, through its enforcement work, has seen significant discrimination issues and complaints. We believe that these specific requirements will best assist covered entities in meeting their obligations and explain to individuals the scope of some of the protections afforded by Section 1557. We seek comment on this approach.

Meaningful Access for Individuals With Limited English Proficiency (§ 92.201)

Overview of § 92.201

Proposed § 92.201 effectuates Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency in health programs and activities of covered entities. About 25 million individuals in the United States, or about 8.5 percent, have limited proficiency in English.[39] These individuals may have been born in other countries or in the United States, such as some Native Americans or children of immigrants.[40] For purposes of this proposed part, an individual with limited English proficiency is a person whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English.

For individuals with limited English proficiency, lack of proficiency in English—and the use of non-English languages—is a direct outgrowth of, and is integrally tied to, their national origins.[41] As the Department of Justice explains, in its role coordinating Federal Departments' enforcement of Title VI, language serves as an identifier of one's national origin by '' 'permit[ing] an individual to express both the personal identity and membership in a community. . . .' '' [42] OCR's experience enforcing Title VI further demonstrates that disadvantaging an individual on the basis of his or her limited English proficiency is inextricably linked to discrimination on the basis of national origin.

It is thus well-established under Title VI and its implementing regulation that a prohibition on national origin discrimination requires covered entities to take reasonable steps to provide meaningful access to individuals with limited English proficiency.[43] As the Supreme Court recognized 40 years ago, the provision of language assistance services is essential to ensure the equality of opportunity promised by nondiscrimination laws. As the Court stated in *Lau* v. *Nichols,* which arose in the context of education,

> [T]here is no equality of treatment merely by providing [limited English proficient] students with the same facilities, textbooks, teachers, and curriculum [as their English speaking peers]; for students who do not understand English are effectively foreclosed from any meaningful education. . . . We know that those who do not understand English are certain to find their classroom experiences wholly incomprehensible and in no way meaningful.[44]

Based on these principles, OCR proposes § 92.201 to require covered entities to take reasonable steps to provide meaningful access to health programs and activities for all persons regardless of national origin. Specifically, proposed paragraph (a) of § 92.201 incorporates the Title VI standard, and paragraph (b) identifies requirements for the Director's evaluation of a covered entity's compliance with paragraph (a). Proposed paragraph (c) contains requirements for language assistance services, and proposed paragraph (d) includes specific requirements for oral interpretation. Proposed paragraph (e) sets forth restrictions on covered entities' use of certain persons to interpret for, or facilitate communication with, individuals with limited English proficiency. Proposed paragraph (f) provides that no individual with limited English proficiency shall be required to accept language assistance services. Each paragraph is described further as follows.

General Requirements (§ 92.201(a), (b) and (c))

Proposed § 92.201(a) adopts the well-established principle that covered entities must take reasonable steps to provide meaningful access to health programs and activities for all individuals with limited English proficiency that they serve or encounter in their health programs or activities.[45] Consistent with our longstanding enforcement of Title VI, we intend the general obligation in paragraph (a) to be a flexible standard that the Director

[39] U.S. Dep't of Commerce, U.S. Census Bureau, American FactFinder, Language Spoken at Home by Ability to Speak English for the Population 5 Years and Older, *supra n. 30* (serving as data source to calculate that 25 million of the 294 million individuals in the United States speak English less than ''very well''). OCR chose the three-year ACS, data (as opposed to the one-year or five-year data) because it best balances the currency and stability of the data.

[40] Dep't of Justice, Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons with Limited English Proficiency; Policy Guidance, 65 FR 50123, 50124 (Aug. 16, 2000) [hereinafter DOJ Policy Guidance, 2000].

[41] *See, e.g.,* 29 CFR 1606.1 (defining an individual's national origin in Equal Employment Opportunity Commission regulations as his or her ancestor's place of origin and an individual's ''physical, cultural or linguistic characteristics'').

[42] DOJ Policy Guidance 2000, 65 FR at 50124 & n.8 (citing *Hernandez* v. *New York,* 500 U.S. 352, 370 (1991) (plurality opinion)). *See also* 29 CFR 1606.1 (Equal Employment Opportunity Commission's definition of national origin, which includes an individual's linguistic characteristics); *Garcia* v. *Gloor,* 618 F.2d 264, 269 (''To a person who speaks only one tongue or to a person who has difficulty using another language when spoken in his home, language might well be an immutable characteristic. . . .'').

[43] *See, e.g.,* HHS LEP Guidance, *supra n. 17* at 68 FR at 47313 (''[T]he failure of a recipient of [F]ederal financial assistance from HHS to take reasonable steps to provide LEP persons with [a] meaningful opportunity to participate in HHS-funded programs may constitute a violation of Title VI and HHS's implementing regulations''); Policy Guidance, Title VI Prohibition against National Origin Discrimination As It Affects Persons with Limited English Proficiency, 65 FR 52762, 52765 (August 30, 2000) (explaining the requirement to take reasonable steps to provide meaningful access and to provide the ''language assistance services necessary to ensure such access. . . .''). *See also* E.O. 13166, *Improving Access to Services for Persons with Limited English Proficiency,* (Aug. 11, 2000) (requiring each Federal Department to improve access to Federally assisted programs and activities by persons with limited English proficiency and to implement a system by which individuals with limited English proficiency can meaningfully access the Departments' Federally conducted programs and activities).

[44] *Lau* v. *Nichols,* 414 U.S. 563, 566 (1974) (requiring a school district with students with limited English proficiency of Chinese origin to take reasonable steps to provide the students with a meaningful opportunity to participate in Federally funded educational programs).

[45] The Department's LEP Guidance provides an in-depth explanation of Title VI's prohibition against national origin discrimination as it affects limited English proficient populations and how recipients can determine what steps are reasonable to provide all individuals with limited English proficiency meaningful access. HHS LEP Guidance, *supra n. 17 at* 68 FR 47311.

ADDENDUM J

substantially limits major life activities only as a result of the attitudes of others toward such impairment; or (C) has none of the impairments defined in paragraph (j)(2)(i) of this section but is treated by a recipient as having such an impairment.

(k) *Program or activity* means all of the operations of—

(1)(i) A department, agency, special purpose district, or other instrumentality of a State or of a local government; or

(ii) The entity of such State or local government that distributes Federal financial assistance and each such department or agency (and each other State or local government entity) to which the assistance is extended, in the case of assistance to a State or local government;

(2)(i) A college, university, or other postsecondary institution, or a public system of higher education; or

(ii) A local educational agency (as defined in 20 U.S.C. 7801), system of vocational education, or other school system;

(3)(i) An entire corporation, partnership, or other private organization, or an entire sole proprietorship—

(A) If assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or

(B) Which is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation; or

(ii) The entire plant or other comparable, geographically separate facility to which Federal financial assistance is extended, in the case of any other corporation, partnership, private organization, or sole proprietorship; or

(4) Any other entity which is established by two or more of the entities described in paragraph (k)(1), (2), or (3) of this section; any part of which is extended Federal financial assistance.

(l) *Qualified handicapped person* means:

(1) With respect to employment, a handicapped person who, with reasonable accommodation, can perform the essential functions of the job in question;

(2) With respect to public preschool elementary, secondary, or adult educational services, a handicappped person (i) of an age during which nonhandicapped persons are provided such services, (ii) of any age during which it is mandatory under state law to provide such services to handicapped persons, or (iii) to whom a state is required to provide a free appropriate public education under section 612 of the Education of the Handicapped Act; and

(3) With respect to postsecondary and vocational education services, a handicapped person who meets the academic and technical standards requisite to admission or participation in the recipient's education program or activity;

(4) With respect to other services, a handicapped person who meets the essential eligibility requirements for the receipt of such services.

(m) *Handicap* means any condition or characteristic that renders a person a handicapped person as defined in paragraph (j) of this section.

(29 U.S.C. 794(b))

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005]

§ 84.4 Discrimination prohibited.

(a) *General.* No qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity which receives Federal financial assistance.

(b) *Discriminatory actions prohibited.* (1) A recipient, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap:

(i) Deny a qualified handicapped person the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified handicapped person an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;

(iii) Provide a qualified handicapped person with an aid, benefit, or service that is not as effective as that provided to others;

(iv) Provide different or separate aid, benefits, or services to handicapped persons or to any class of handicapped persons unless such action is necessary to provide qualified handicapped persons with aid, benefits, or services that are as effective as those provided to others;

(v) Aid or perpetuate discrimination against a qualified handicapped person by providing significant assistance to an agency, organization, or person that discriminates on the basis of handicap in providing any aid, benefit, or service to beneficiaries of the recipients program or activity;

(vi) Deny a qualified handicapped person the opportunity to participate as a member of planning or advisory boards; or

(vii) Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving an aid, benefit, or service.

(2) For purposes of this part, aids, benefits, and services, to be equally effective, are not required to produce the identical result or level of achievement for handicapped and nonhandicapped persons, but must afford handicapped persons equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement, in the most integrated setting appropriate to the person's needs.

(3) Despite the existence of separate or different aids, benefits, or services provided in accordance with this part, a recipient may not deny a qualified handicapped person the opportunity to participate in such aids, benefits, or services that are not separate or different.

(4) A recipient may not, directly or through contractual or other arrangements, utilize criteria or methods of administration (i) that have the effect of subjecting qualified handicapped persons to discrimination on the basis of handicap, (ii) that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program or activity with respect to handicapped persons, or (iii) that perpetuate the discrimination of another recipient if both recipients are subject to common administrative control or are agencies of the same State.

(5) In determining the site or location of a facility, an applicant for assistance or a recipient may not make selections (i) that have the effect of excluding handicapped persons from, denying them the benefits of, or otherwise subjecting them to discrimination under any program or activity that receives Federal financial assistance or (ii) that have the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity with respect to handicapped persons.

(6) As used in this section, the aid, benefit, or service provided under a program or activity receiving Federal financial assistance includes any aid, benefit, or service provided in or through a facility that has been constructed, expanded, altered, leased or rented, or otherwise acquired, in whole or in part, with Federal financial assistance.

(c) *Aids, benefits, or services limited by Federal law.* The exclusion of nonhandicapped persons from aids, benefits, or services limited by Federal statute or executive order to handicapped persons or the exclusion of a specific class of handicapped persons from aids, benefits, or services limited by Federal statute or executive order to a different class of handicapped persons is not prohibited by this part.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005]

§ 84.5 Assurances required.

(a) *Assurances.* An applicant for Federal financial assistance to which this part applies shall submit an assurance, on a form specified by the Director, that the program or activity will be operated in compliance with this part. An applicant may incorporate these assurances by reference in subsequent applications to the Department.

(b) *Duration of obligation.* (1) In the case of Federal financial assistance extended in the form of real property or to provide real property or structures on the property, the assurance will obligate the recipient or, in the case of a subsequent transfer, the transferee, for