



214 Massachusetts Avenue, NE  
Washington, DC 20002  
(202) 546-4400  
heritage.org

October 3, 2022

Secretary Xavier Becerra  
U.S. Department of Health and Human Services  
Office for Civil Rights, Attention: 1557 NPRM (RIN 0945–AA17)  
Hubert H. Humphrey Building  
Room 509F  
200 Independence Avenue SW  
Washington, DC 20201

Dear Secretary Becerra,

In the proposed rule “Nondiscrimination in Health Programs and Activities” [RIN: 0945–AA17], the Department revises its current interpretation and implementation of Section 1557 of the Patient Protection and Affordable Care Act.<sup>1</sup> A number of those reinterpretations entail significant implications for health insurers.<sup>2</sup> The regulatory impact analyses accompanying the proposed rule do not fully account for those implications.

With respect to health insurers, the proposed rule would:

1. Expand the scope of applicability
2. Assign the burden of proof to covered entities
3. Impose new regulatory oversight on numerous business decisions
4. De facto regulate the practice of medicine and health insurance coverage
5. Increase compliance burdens and legal jeopardy

Should the proposed rule be finalized in its current form, these changes will have significant implications for the business of health insurance.

### **Expanded scope of applicability**

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<sup>1</sup> Pub. L. 111-148, codified at 42 USC 18116.

<sup>2</sup> Centers for Medicare and Medicaid Services; Office for Civil Rights, Office of the Secretary, HHS, “Nondiscrimination in Health Programs and Activities,” 87 FR 47824-47920.

The statutory language of Section 1557 specifies that its provisions of apply to “any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance.”

The 2020 rule specified that Section 1557 applied “to such entity’s operations only to the extent any such operation receives Federal financial assistance.”<sup>3</sup> Thus, a health insurer was a covered entity under Section 1557 only with respect to the portion of its business that received federal financial assistance.

The proposed rule expands that scope of applicability to encompass all of a health insurer’s business if any portion receives federal financial assistance, either directly or indirectly.<sup>4</sup> In the preamble to the proposed rule, the Department emphasizes that, “...we propose to apply this rule to all the operations of a recipient entity principally engaged in the provision or administration of health insurance coverage or other health-related coverage.” The Department goes on to illustrate, “For example, recipient health insurance issuers principally engaged in providing or administering health insurance coverage would be covered for health insurance they provide to a fully insured group health plan and also for third party administrator activities that they are responsible for providing in a self-funded group health plan.”<sup>5</sup>

Thus, the proposed rule would apply to all of an insurer’s business even if only a small portion is found to be in receipt of federal financial assistance.

### **Assigning the burden of proof to covered entities**

In its discussion of enforcement, the Department states its intent to use “circumstantial evidence” of discrimination, including “evidence of disparate impact,” and that the burden of proof is effectively assigned to the covered entity which “must articulate a legitimate, nondiscriminatory reason for its actions.”<sup>6</sup>

The proposed new § 92.303 also incorporates by reference the “procedures are found at 45 CFR 80.6 through 80.11 and part 81 of this subchapter,” and for the Age Act the procedures “found at 45 CFR 91.41 through 91.50.”<sup>7</sup> Those procedures include requirements that covered entities submit to the Department compliance reports and data and authorize the Department to conduct periodic compliance reviews of covered entities.<sup>8</sup>

The Department is effectively declaring that its enforcement of the provisions of the proposed rule will be based on the presumption that any business decisions made a covered entity is either intentionally discriminatory or has an impermissible discriminatory effect, unless and until the entity can demonstrate otherwise to the Department’s satisfaction.

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<sup>3</sup> 45 CFR §92.3(b) and (c).

<sup>4</sup> “Nondiscrimination in Health Programs and Activities,” proposed 45 CFR § 92.2 and § 92.4.

<sup>5</sup> Ibid. pp. 47844 and 47845.

<sup>6</sup> Ibid. pp. 47827, 47865, and 47870.

<sup>7</sup> Ibid. proposed 45 CFR § 92.203.

<sup>8</sup> See: 45 CFR § 80.6, § 80.7, and § 91.41.

## **Imposition of new regulatory oversight on numerous business decisions**

With respect to the ability of health insurers to deny, cancel, limit, or refuse to issue or renew health insurance coverage, Sec. 1557 (and this proposed rule) add nothing to other, existing federal and state laws and regulations that govern such matters.

However, this proposed rule would go further than those other laws by imposing new “non-discrimination” tests on insurer business decisions that resulted in the denial or limitation of payment for a claim, on variations in cost sharing under the terms of a health plan, or on the imposition of (unspecified) “other limitations or restrictions on coverage.”<sup>9</sup>

The proposed rule would also impose (unspecified) non-discrimination tests on insurance “benefit designs.”<sup>10</sup> In the preamble, the Department writes that, “the Department does not propose defining these terms in this rule and intends to interpret them broadly. Examples of benefit design features include, but are not limited to, coverage, exclusions, and limitations of benefits; prescription drug formularies; cost sharing (including copays, coinsurance, and deductibles); utilization management techniques (such as step therapy and prior authorization); medical management standards (including medical necessity standards); provider network design; and reimbursement rates to providers and standards for provider admission to participate in a network.”<sup>11</sup>

Thus, the Department is announcing its intent to engage in expansive and detailed regulation of numerous insurer business decisions in an arbitrary and capricious manner.

In the same vein, the proposed rule also includes new sections that would impose non-discrimination tests on “the use of clinical algorithms in decision-making,” and on “the delivery of health programs and activities through telehealth services.”<sup>12</sup>

In addition, the preamble states that, “Plan choices regarding provider networks may also violate Section 1557.”<sup>13</sup> It further comments that, “Provider networks that limit or deny access to care for individuals with certain disabilities, such as by excluding certain providers from the network that treat high-cost enrollees, raise discrimination concerns.”

Having raised the topic, the Department then states that, “we do not propose to prescribe specific network adequacy requirements for covered entities under this rule. However, to ensure compliance with Section 1557, payers must develop their networks in a manner that does not discriminate against enrollees on the basis of race, color, national origin, sex, age, or disability.”<sup>14</sup>

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<sup>9</sup> “Nondiscrimination in Health Programs and Activities,” proposed 45 CFR § 92.207(b)(1).

<sup>10</sup> Ibid. proposed 45 CFR § 92.207(b)(2).

<sup>11</sup> Ibid. p. 47869.

<sup>12</sup> Ibid. proposed 45 CFR § 92.210 and § 92.211.

<sup>13</sup> Ibid. p. 47877.

<sup>14</sup> Ibid. p. 47878.

The Department concludes, “We generally seek comment on how Section 1557 might apply to: provider networks; how provider networks are developed, including factors that are considered in the creation of the network and steps taken to ensure that an adequate number of providers and facilities that treat a variety of health conditions are included in the network; the ways in which provider networks limit or deny access to care for individuals on the basis of race, color, national origin, sex, age, or disability; and the extent to which the lack of availability of accessible medical diagnostic equipment in a provider network limits or denies access to care for individuals with disabilities.”<sup>15</sup>

In sum, the Department has signaled its interest in extending its construct of “non-discrimination” tests to plan network decisions in future rule making.

The collective effect of all the foregoing would be to impose an expansive, arbitrary, and capricious new regulatory regime on numerous, operational level business decisions of health insurers.

### **De facto regulation of medical practice and health insurance coverage**

A particularly controversial feature of the proposed rule is the Department’s decision to reinterpret the Title IX prohibition of discrimination “on the basis of sex” to include “discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity.”<sup>16</sup>

Setting aside the issue of the legitimacy of that reinterpretation, the most significant implication for health insurers is that it provides the predicate for the Department to assert *de facto* authority over medical practice and over the relationship between health insurance and medical care under the pretext of implementing and enforcing Title IX and the other civil rights laws that are incorporated by reference in Section 1557.<sup>17</sup>

Specifically, in its proposed § 92.206 the Department asserts authority to establish parameters for the practice of medicine by health care providers in connection with “gender transition or other gender-affirming care,” and does the same with respect to insurer coverage and payment practices in its proposed § 92.207.

Furthermore, the Department categorically states in § 92.206(c) that “a provider’s belief that gender transition or other gender-affirming care can never be beneficial for such individuals (or its compliance with a state or local law that reflects a similar judgment) is not a sufficient basis for a judgment that a health service is not clinically appropriate.”

Similarly, the Department categorically states in § 92.207(b)(4) that an insurer must not, “have or implement a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care.”

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<sup>15</sup> Ibid. p. 47878.

<sup>16</sup> Ibid. proposed 45 CFR § 92.201(a)(2).

<sup>17</sup> Pub. L. 111-148 § 1557, codified at 42 U.S.C. § 18116.

In discussing these provisions, the Department states that, “claims of medical necessity that are not based upon genuine medical judgments will be considered evidence of pretext for discrimination. For example, issuers have historically excluded services related to gender affirming care for transgender people as experimental or cosmetic (and therefore not medically necessary). Characterizing this care as experimental or cosmetic would be considered evidence of pretext because this characterization is not based on current standards of medical care.”<sup>18</sup>

Thus, in the proposed rule the Department is explicitly asserting that it has authority under Section 1557 to regulate, in detail, the practice of medicine and the structure of health insurance coverage according to its own determination of what is “appropriate” and “non-discriminatory,” along with authority to definitively determine what is, or is not, the “current standard of medical care.”

While in the proposed rule the Department makes this assertion most explicitly with respect to “gender transition or other gender-affirming care,” there is no limiting principle preventing the Department from, in the future, asserting and exercising the same, or similar, claims of authority with respect to other medical practices, standards of care, or health insurance coverages.

Indeed, the proposed § 92.207(d) states that, “The enumeration of specific forms of discrimination in paragraph (b) of this section does not limit the general applicability of the prohibition in paragraph (a) of this section.”

Given the overall structure of the proposed rule, the Department’s stated intention to apply “disparate impact” analyses, and the fact that the proposed rule also incorporates a sweeping definition of “disability” under the Americans with Disabilities Act, it is largely a matter of when, not if, the Department will assert the same authority with respect to other medical conditions, practices, and health insurance coverages.<sup>19</sup>

Indeed, there are those who have advocated for years that the reference to the Americans with Disabilities Act in Section 1557 should be used as an avenue for regulating insurers with respect to numerous other medical conditions in the same fashion as the proposed rule would regulate them with respect to gender transition treatments.<sup>20</sup>

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<sup>18</sup> “Nondiscrimination in Health Programs and Activities,” p. 47874.

<sup>19</sup> Ibid. The definition of “disability” in the proposed 45 CFR § 92.4 states, “*Disability* means, with respect to a person, a physical or mental impairment that substantially limits one or more major life activities of such person; a record of such an impairment; or being regarded as having such an impairment, as defined and construed in the Rehabilitation Act, 29 U.S.C. 705(9)(B), which incorporates the definition of disability in the ADA, 42 U.S.C. 12102, as amended and adopted at 28 CFR 35.108.” The referenced 42 U.S.C. 12102 states in (2)(B) that, “a major life activity also includes the operation of a major bodily function, including but not limited to, functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, respiratory, circulatory, endocrine, and reproductive functions.” The referenced 28 CFR 35.108 states in (c)(1)(ii) that, “The operation of a *major bodily function*, such as the functions of the immune system, special sense organs and skin, normal cell growth, and digestive, genitourinary, bowel, bladder, neurological, brain, respiratory, circulatory, cardiovascular, endocrine, hemic, lymphatic, musculoskeletal, and reproductive systems. The operation of a major bodily function includes the operation of an individual organ within a body system.”

<sup>20</sup> See: Douglas Jacobs, “The Section 1557 Regulation: What’s Missing, And How We Can Include It,” Health Affairs Blog, September 21, 2015, <http://healthaffairs.org/blog/2015/09/21/the-section-1557-regulation-whats-missing-and-how-we-can-include-it/>, and Douglas Jacobs and Wayne Turner, “Nondiscrimination And Chronic

## **Increase in compliance burdens and legal jeopardy**

The proposed rule would impose new compliance burdens on covered entities, including health insurers. A covered entity would be required to designate an employee as its “Section 1557 Coordinator” and to create and implement various written policies and procedures.<sup>21</sup> Among those are grievance procedures “that provide for “the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557 or this part,” and reasonable modification procedures that describe the entity’s “process for making reasonable modifications to its policies, practices, or procedures when necessary to avoid discrimination on the basis of disability.”

The proposed rule would also require that a covered entity periodically conduct (and document) staff training on all the various required policies and procedures, as well as comply with specified documentation and record retention requirements.<sup>22</sup>

Furthermore, the Department notes that enforcements mechanisms include a private right of action under the statutes incorporated by reference in Section 1557.<sup>23</sup>

## **Effect on health insurance markets**

Health insurers that are covered entities under the proposed rule could face substantial costs. Not only would they incur compliance costs, but they could also incur significant additional claims costs as a result of the proposed rule forcing them to alter their coverages and business practices. Higher claims costs are, in turn, the principal driver of higher premiums.

Furthermore, given that under the proposed rule the Department would engage in expansive and detailed regulation of numerous insurer business decisions in an arbitrary and capricious manner, any insurer that is a covered entity should expect to face heightened business risks and increased liability exposure.

There are three lines of private insurance that meet the criteria of the proposed rule for receiving federal financial assistance; Medicaid managed care plans, Medicare Advantage plans, and individual market Qualified Health Plans (QHPs). While federal funding is delivered in different ways for each of those three product lines, the common denominator is that federal funding for all three comes from mandatory appropriations. As a practical matter, that means that insurers offering one or more of those coverages will be able to pass back onto the federal government the bulk of any additional costs that they incur due to the proposed rule.

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Conditions -- The Final Section 1557 Regulation,” Health Affairs Blog, July 20, 2016, <https://www.healthaffairs.org/doi/10.1377/forefront.20160720.055888>.

<sup>21</sup> Ibid. proposed 45 CFR § 92.7 and § 92.8.

<sup>22</sup> Ibid. proposed 45 CFR § 92.9.

<sup>23</sup> Ibid. p. 47885.

In contrast, coverages and services that do not receive federal financial assistance—most notably, fully insured and self-insured employer group plans—have to pass any cost increases onto customers and enrollees.

Given the foregoing, it is reasonable to expect that finalizing the proposed rule in its current form will cause health insurers to reevaluate their current business strategies and product offerings.

The first, and most fundamental, decision each insurer will have to make is whether it is comfortable with being a covered entity subject to these new regulations.

While those decisions cannot be projected with complete certainty, they can be reasonably approximated. That can be done by assessing the extent of each insurer's regulatory exposure—a good metric for which is the distribution of insurer enrollment by product line—and assigning probabilities accordingly.

It stands to reason that an insurer with a large share of its enrollment in products receiving federal financial assistance is more likely to continue offering those products. Conversely, it also stands to reason that an insurer with a small share of its enrollment in products receiving federal financial assistance is more likely exit those products and markets.

The enrollment profiles of two major national carriers illustrate the point:

- Centene is the fourth largest insurer nationally and is the carrier with both the largest number of Medicaid Managed Care enrollees and the largest enrollment in QHPs. Fully, 97 percent of Centene's enrollees are in plans receiving federal financial assistance.
- Cigna is the sixth largest insurer nationally and the carrier that services the fourth largest number of enrollees in self-insured employer plans. Only six percent of Cigna's enrollees are in plans receiving federal financial assistance.

Given that Centene already operates almost entirely as a government contractor and can expect to transfer any costs resulting from the proposed regulation back onto price-insensitive payers (government entitlement programs), there is little reason to expect Centene to alter its current business strategy in response to the proposed rule.

In contrast, given that enrollment in plans receiving federal financial assistance constitutes a very small part of Cigna's current business, but under the proposed rule would expose all of its other business to increased costs, uncertainty and liability, Cigna's most prudent course of action would be to divest or discontinue those affected plans.

Thus, finalizing the proposed rule in its current form can reasonably be expected to trigger a reorganization of the private health insurance industry into two distinct segments; insurers that are covered entities and insurers that are not. That in turn has implications for market competition and coverage availability.

To illustrate further, the following table provides data on 19 Blue Cross and Blue Shield carriers that currently offer QHPs in 30 states where they are a BCBS licensee, but for whom their plans receiving federal financial assistance account for less than one-quarter of their total enrollment.

**BCBS Licensees That Offer QHPs and Have Less Than One-Quarter of Their Total Enrollment in Plans Receiving Federal Assistance**

Parent Company	State(s) Where BCBS Licensee	Total Enrollment in Comprehensive Coverage Plans*	Subset Enrolled in Plans Receiving Federal Assistance**	Share Receiving Federal Assistance
Premera Blue Cross	AK and WA	2,594,665	112,506	4%
Blue Cross Blue Shield of Massachusetts	MA	2,890,949	139,079	5%
Wellmark, Inc.	IA and SD	1,343,283	72,852	5%
Blue Cross and Blue Shield of Kansas City	KS (2 Counties) and MO (30 Counties)	675,962	41,593	6%
CareFirst BlueCross BlueShield	MD, DC and VA (4 Counties)	3,044,350	272,358	9%
Blue Cross Blue Shield of Vermont	VT	170,710	15,536	9%
Cambia Health Solutions, Inc.	ID, OR, WA, UT	1,995,591	183,545	9%
Noridian Mutual Insurance Company	ND	279,431	26,358	9%
Blue Cross and Blue Shield of Kansas, Inc.	KS (All but 2 Counties)	561,814	56,016	10%
Louisiana Health Service & Indemnity Company	LA	1,436,188	153,560	11%
Blue Cross and Blue Shield of Alabama	AL	2,589,149	309,831	12%
Health Care Service Corporation	IL, MT, NM, OK and TX	16,722,380	2,104,880	13%
USABLE Mutual Insurance Company	AR	1,766,896	244,549	14%
Capital BlueCross	PA (21 Counties)	752,318	113,478	15%
Blue Cross Blue Shield of Michigan Mutual Insurance Company	MI	5,069,389	869,490	17%
Blue Cross of Idaho Health Service, Inc.	ID	566,148	98,502	17%
Blue Cross & Blue Shield of Rhode Island	RI	405,728	79,648	20%
Blue Cross Blue Shield of Arizona, Inc.	AZ	1,644,444	337,413	21%
Highmark, Inc.	DE, NY (21 Counties), OH (1 County), PA (63 Counties) and WV	4,616,541	1,018,995	22%

**Source:** Mark Farrah Associates (www.markfarrah.com), compiled using data from NAIC, CA-DMHC, CMS



and other state government and private sources.

**Notes:**

\* Enrollment figures are for comprehensive coverage plans only and do not include enrollment in supplement plans (dental, vision, etc.).

\*\* Combined enrollment in individual market, Medicare Advantage and Medicaid managed care plans.

Furthermore, six of those carriers (collectively offering coverage in 11 states) are organized as member-owned mutual insurance companies.<sup>24</sup> Unlike traditional non-profit Blues, they are not subject to “community benefit” requirements that could potentially complicate or impede their exiting a state or a line of business.

In fact, several of them previously avoided or exited the ACA exchange market due to unfavorable conditions. For instance, Wellmark has never offered exchange coverage in South Dakota and did not offer exchange coverage in Iowa until 2017, then exited in 2018, but returned in 2019. Similarly, Health Care Service Corporation withdrew its New Mexico Blue Cross subsidiary from that state’s exchange in 2016, though it returned the following year. Blue Cross and Blue Shield of Nebraska exited the exchange in 2017 and has not returned. Currently, only two percent of that company’s enrollees are receiving federal assistance (consisting of few than 7,000 individuals in Medicare Advantage plans). Blue Cross & Blue Shield of Mississippi is also a mutual insurer. It has never offered exchange coverage and has no Medicare Advantage or Medicaid managed care enrollees.

Any resulting insurer exits could also have significant localized effects. For instance, Blue Cross Blue Shield of Vermont is one of only two insurers offering coverage in that state’s exchange. The same holds true for both Noridian in North Dakota and Highmark in West Virginia. Also, Highmark is the only insurer offering exchange coverage in Delaware. Blue Cross and Blue Shield of Alabama is the only insurer offering exchange coverage in 63 of that state’s 67 counties.

The above table is not exhaustive. There also are non-Blue Cross carriers with less than one-quarter of their enrollment in affected plans, as well as 30 insurers with between 25 percent and 50 percent of their total enrollment is in affected plans. Some of those insurers would likely also take action to avoid being covered entities.

In sum, the proposed rule is likely to be far more costly to insurers than the Department projects, to result in reduce insurer competition in the exchange QHP, Medicaid managed care, and Medicare Advantage markets, and to further dissuade currently unaffected insurers from entering any of those markets. That would, in turn, result in fewer coverage options for exchange enrollees and Medicare beneficiaries, and fewer bidders for state Medicaid managed care contracts.

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<sup>24</sup> Blue Cross Blue Shield of Michigan Mutual Insurance Company, Blue Cross of Idaho Health Service, Inc., Health Care Service Corporation, Noridian Mutual Insurance Company, USABLE Mutual Insurance Company, and Wellmark, Inc.

In light of the foregoing, the Department should not finalize the proposed rule before conducting and publishing additional regulatory impact analyses of the effect of this rule on insurer competition in at least the Medicare Advantage market and the exchange QHP market, including at the state and county level.

Sincerely,

*/Edmund F. Haislmaier/*

Edmund F. Haislmaier  
Preston A. Wells, Jr. Senior Research Fellow  
Center for Health and Welfare Policy