



December 22, 2020

The Honorable Alex Azar  
Secretary  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-9914-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

**RE: “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations,” Proposed Rule.**

Dear Secretary Azar and Administrator Verma:

The National Organization for Rare Disorders (NORD) thanks the U.S. Department of Health and Human Services (HHS) for the opportunity to submit comments on this proposed rule. NORD is a unique federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. We are committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services. The more than 25 million Americans that are impacted by rare diseases could be negatively impacted by this proposed rule and we urge HHS to only finalize this rule with the major changes outlined below.

***Privatizing Marketplaces - 155.221(j)***

On November 1, the Centers for Medicare and Medicaid Services (CMS) approved Georgia’s section 1332 waiver, endorsing a dramatic departure from the health plan shopping and enrollment experience currently available to people nationwide through either HealthCare.gov or a state-based marketplace. If implemented, the approved waiver will end Georgia’s participation in HealthCare.gov, through which half a million Georgians enroll, and instead privatize the enrollment function, with consumers able to shop only through agents and brokers and could leave individuals particularly dependent on web brokers. This waiver is bound to lead to lower enrollment in comprehensive coverage through sheer consumer confusion during the transition, brokers’ reluctance to refer people to plans that don’t pay commissions or to Medicaid, and increased pressure for consumers to enroll in short-term and other sub-par plans.

The proposed rule would allow other states to make the same radical change without going through the waiver process. This would deprive consumers, including the rare disease patients

we represent, of a public comment period before such a change is made. Public input is crucial for state marketplaces to ensure that diverse voices are heard, including from the more than 1 in 10 Americans living with a rare disease who have a unique perspective on health care. In addition, not only would privatizing the marketplace harm consumers, allowing states to do so without a waiver clearly violates Affordable Care Act (ACA) requirements. Under this rule, the state would provide a rudimentary website that displays basic plan information without a means to enroll, then direct people to private websites to complete the application. This is in violation of the statutory requirement in section 1311(d)(2) of the ACA, which requires a marketplace to “make available qualified health plans to qualified individuals.” In general, individuals would not be able to enroll in qualified health plans through the state website.

NORD fears that with this proposal, many patients could be lost in the transition between the state and private websites. For example, Nevada recently transitioned to a new enrollment platform and while the transition went smoothly, enrollment declined in the first year.<sup>1</sup> For rare disease patients who require daily, weekly or monthly medications and/or health care provider engagement, this sudden loss in coverage could result in their being unable to meet with their provider or get prescriptions filled, leading to worse health outcomes, including hospitalization or death.

In addition, this proposal is problematic as patients who shop on HealthCare.gov can trust that they are purchasing a comprehensive health insurance plan, known as a qualified health plan (QHP), that will allow them to manage their health conditions. This is extremely important for rare disease patients, as their health care can be complex and comprehensive, affordable, quality care is crucial to maintaining their overall health. However, under this new proposal, issuers and brokers could sell QHPs alongside other types of plans, often known as “skinny plans” or “short term plans” that discriminate against people with pre-existing conditions and will not cover enrollees’ medical expenses if they get sick. We strongly oppose this provision.

### ***Reducing the User Fee - 156.50***

The proposed rule would cut the federal marketplace user fee by 25 percent, from 3 percent to 2.25 percent and would cut the user fee for state-based marketplaces that use the federal platform from 2.5 percent to 1.75 percent. We oppose this provision.

The marketplace user fee — a fixed percentage of premium revenue paid by insurers — supports critical functions, including the operation and improvement of the HealthCare.gov website, the Marketplace call center, the Navigator program, consumer outreach, and advertising. This proposal would shift resources away from HealthCare.gov and may increase the use of web-based brokers that can offer non-compliant plans.

---

<sup>1</sup> <https://www.healthinsurance.org/nevada-state-health-insurance-exchange/>

The proposed rule's rationale for the cut is that the lower user fee would be sufficient to fund current marketplace activities. But current activities are inadequate. Under the current Administration, CMS has virtually ceased marketing and outreach, and has slashed funding for Navigators, all of which are core marketplace functions funded by user fees. The COVID-19 pandemic has underscored the importance of having sufficient outreach and enrollment in order to enroll consumers in insurance. Coverage has never been more important, so rather than cutting the user fee, it should be *increased* to 3.5 percent (the level in effect prior to 2020) to restore outreach and enrollment assistance programs and to fund continued improvements to HealthCare.gov, including technological enhancements and improved customer service.

### ***Promoting the Use of Direct Enrollment Among Assistors - 155.220(c)(3)(iii)(A)***

The proposed rule would encourage Navigators and Certified Application Counselors to use direct enrollment entities. This additional form of privatization of HealthCare.gov functions would direct assistors to web brokers that could sell products other than QHPs in ways that might be confusing to less experienced assistors and consumers. Likewise, these avenues are not guaranteed to facilitate enrollment in plans that don't pay a commission, leading assistors on a time-consuming chase across websites to enroll in the right plan.

The Administration's justification for the proposal is that these websites have additional functionality that would be useful to assistors. Rather than shifting to a more privatized model, this points to the need to further invest in HealthCare.gov to expand its functionality for assistors and consumers. More of an investment in the existing navigators and assistors could help increase the number of Americans, including rare disease patients, that are covered by accessible, affordable, and adequate health care. We oppose this provision.

### ***Weakening the 1332 Waiver Protections - 31 CFR Part 33 and 45 CFR Part 155***

The 1332 waiver's statutory guardrails require that waivers cover at least as many people, with coverage at least as comprehensive and affordable as would be the case without the waiver, without increasing the federal deficit. In 2018 guidance, the Administration attempted to undercut these statutory requirements in several ways. It then issued a concept paper encouraging states to submit waiver proposals that would weaken protections for people with pre-existing conditions, cut financial assistance for consumers with low incomes and/or older people, and/or increase out-of-pocket costs, implying that such waivers might be approvable under the new guidance.

The proposed rule attempts to codify the 2018 guidance, for the most part, by reference rather than by crafting concrete regulatory language. Codifying this non-regulatory policy by reference is not only bad policy on the merits but is also legally dubious (as is the guidance itself, which deviates from the plain meaning of the statute).

NORD is opposed to any changes to the 1332 statute that would weaken protections for pre-existing conditions or increase patient out-of-pocket costs. Quality, affordable health care is essential for patients with a rare disease to maintain their treatments and overall health. This proposal would jeopardize our patient's health by encouraging states to submit waiver proposals that would make comprehensive care less accessible. We strongly oppose this provision.

***Continues a Policy That Raises Premiums and Out-of-Pocket Costs - 156.130(e)***

The proposed rule also continues the Administration's 2019 change in the formula used to calculate premium tax credits, which cut financial assistance for millions of people. If continued, the formula change will have an even greater impact in 2022, raising premiums by an estimated 4.7 percent for most subsidized marketplace consumers after accounting for their tax credits (compared to about 2.7 percent this year). That amounts to a \$360 annual premium increase for a family of four with \$80,000 in income.

The same formula change also increases the limit on consumers' total out-of-pocket expenses, which applies to both marketplace and employer plans. In 2022, that limit will be \$400 higher for an individual, and \$800 higher for families, than if the 2019 change were reversed.

Rare disease patients already often face a high financial burden due to their costly treatments and necessary medical appointments to maintain their overall health. According to a 2019 NORD survey, 76% of all respondents experienced financial challenges due to their own or their family member's rare diagnosis.<sup>2</sup> As a result, we strongly urge you to reverse the 2019 formula change.

We once again thank you for the opportunity to submit comments on this proposed rule. We look forward to continuing to work with HHS to ensure rare disease patients have access to comprehensive, affordable, quality health care. For questions regarding NORD or the above comments please contact Rose Gallagher at [rgallagher@rarediseases.org](mailto:rgallagher@rarediseases.org).

Sincerely,



Heidi Ross  
Director of Policy

---

<sup>2</sup> [https://rarediseases.org/wp-content/uploads/2020/11/NRD-2088-Barriers-30-Yr-Survey-Report\\_FNL-2.pdf](https://rarediseases.org/wp-content/uploads/2020/11/NRD-2088-Barriers-30-Yr-Survey-Report_FNL-2.pdf)