



October 3, 2022

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Blvd  
Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

The National Health Council (NHC) appreciates the opportunity to provide comments on the proposed rule Nondiscrimination in Health Programs and Activities, updating the implementation of Section 1557 of the Affordable Care Act (ACA) (Section 1557). Of primary importance is that this proposed rule significantly addresses the loss of civil rights protections that many patients faced under the previous rule from 2020. Reinstating many of the policies from the 2016 rule and adding additional protections will make considerable progress in assuring access to coverage and care for millions of Americans.

Created by and for patient organizations more than 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable health care. Made up of more than 150 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic drug, and payer organizations.

There are many provisions that NHC supports and thanks the Centers for Medicare & Medicaid Services (CMS) for including in this proposed rule. These include issues around scope of protections under 1557, patient information and access, and insurance coverage.

### **Scope of Protections**

The NHC strongly supports the inclusion of provisions to restore regulatory provisions recognizing that Section 1557 applies to Medicaid, Medicare, the ACA's state and federal Marketplaces and the plans sold through them, and other commercial health plans if the insurer receives any form of federal financial assistance. This expansion will ensure a broad interpretation of 1557 to include a wide range of insurers and providers. This is consistent with the statutory language and the intent of the ACA to ensure broad access to and coverage of health care. In addition, the provisions clarifying antidiscrimination provisions for specific populations are necessary and welcome including provisions to:

- Affirm gender-based and disability and accessibility antidiscrimination policies;
- Clarify language access requirements; and
- Include sex characteristics or orientation in coverage and restores coverage for gender identity or stereotype and pregnancy in definition of “sex.”

### **Patient Notification and 1557 Coordinators**

After the changes in the 2020 rule, patients were not required to receive information about their rights under 1557. The restoration of requirements that information about 1557 protections be made widely available and posted publicly will help patients understand their rights and act when those rights are violated. This critical information is of vital importance to patients. We strongly support this provision and the requirements for when this notice must be made available. We also recommend that if a covered entity operates across multiple states, it must provide the notice in not merely the top 15 languages in the aggregate (that is, adding to the top 15 languages across all the states) but rather the top 15 languages in each state. We also recommend that OCR require covered entities to require the notice include a large print statement, in at least 18-point font, in addition to the top 15 languages. This will assist individuals with vision impairments to understand the importance of the notice. We also suggest that OCR develop and provide covered entities with model notices and translated information in the relevant languages that will be needed across the country. These notices should relate to the different types of publications they are included on; that is, a notice would likely be different for a consent form versus information about a public health emergency versus a notice about one’s rights or benefits. Finally, the NHC requests that CMS engage affected communities including patients and their representatives to codevelop understandable information and identify the best ways to communicate rights and responsibilities in ways that meet them where they are and in a manner that will be useful.

The inclusion of requirements that 1557 coordinators be in place in all covered entities will also be of assistance to patients who are facing discriminatory practices. We urge CMS to include provisions that assure that patients know of the existence of 1557 coordinators and how to access them if they face discrimination. Too often, in the middle of a problematic experience, it is difficult for a patient to know the right course of action unless they are socialized to protections before the experience. Once again, we encourage CMS to collaborate with patients to identify the most successful ways to educate people about this important resource.

Finally, the proposed rule includes a question about whether 1557 coordinators should be required in smaller businesses, and we recommend that they are indeed included. No matter the size of the plan or provider, people need redress when facing discrimination.

### **Insurance Coverage**

We strongly support the proposed provisions to prohibit discriminatory plan benefit design and marketing practices by insurers. Particularly, we support the following provisions:

- Covered entities could not—on the basis of race, color, national origin, sex, age, or disability—deny, cancel, limit, or refuse to issue or renew coverage; deny or limit coverage of a claim; or impose additional cost sharing or other limitations or restrictions on coverage;
- Covered entities could not adopt marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability; and
- Covered entities also could not have or implement benefit designs that do not provide or administer coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities. An example of this would be if a plan required utilization management for someone in the community but not for someone in an institution.

The NHC supports the proposed definition of benefit design to include, but not be 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.” Similarly, we support your definition of marketing practices to “broadly include, for example, activities designed to encourage individuals to participate or enroll in particular health plans or certain types of plans, or to discourage them from doing so, and activities that steer or attempt to steer individuals towards or away from a particular plan or certain types of plans.”

As described in the proposed rule’s preamble, utilization management can include prior authorization, step therapy (or “fail-first”), and durational or quantity limits. While CMS states that utilization management controls “are standard industry practices that are permitted under Section 1557,” we are pleased that you have added:

*“...as long as they are applied in a neutral, nondiscriminatory manner and are not otherwise prohibited under other applicable Federal and state law. Excessive use or administration of utilization management tools that target a particular condition that could be considered a disability or other prohibited basis could violate Section 1557. For example, prescription drug formularies that place utilization management controls on most or all drugs that treat a particular condition regardless of their costs without placing similar utilization management controls on most or all drugs used to treat other conditions may be discriminatory under this section. Similarly, benefit designs that place utilization management controls on most or all services that treat a particular disease or condition but not others may raise concerns of discrimination. Where there is an alleged discriminatory practice or action, the covered entity would be expected to provide a legitimate, nondiscriminatory reason, based on clinical evidence, for the practice.”*

The inclusion of benefit design under 1557 is an important expansion of protections. Too often, barriers to health care can be based in those decisions. Assuring that plan design practices support equitable access to health care will benefit patients. Without

these provisions, patients could be subject to discriminatory benefit designs. Examples of plan design elements that we hope would be eliminated through 1557 protection include, placing all or most prescription drugs used to treat a specific condition on a health plan's highest cost formulary tier, applying age limits to services that have been found to be clinically effective at all ages, or requiring prior authorization or step therapy for all or most medications in drug classes regardless of medical evidence.

### **Clinical Algorithms**

We agree with HHS that clinical algorithms have the potential to be discriminatory and particularly harmful to patients from marginalized communities, as they may dictate that certain patients must be more ill than other patients before they can receive treatment for life-threatening conditions such as kidney disease and heart failure. We urge CMS to adopt a broad definition of "clinical algorithms" to include all clinical automated decision-making processes. In addition, we urge CMS to monitor implementation of this provision to assure that it is being correctly implemented broadly.

### **Telehealth**

We support the proposed rule's provision on telehealth. Telehealth is a tool to improve access to health care for many patients. As the use of telehealth expanded during the COVID-19 pandemic, access has not been equitable for individuals with limited English proficiency and people with disabilities due to the telehealth platforms themselves being inaccessible. Therefore, we recommend that HHS require telehealth platforms to allow a third-party interpreter or use of auxiliary aids and services. Second, all of the communication about telehealth that occurs prior to a telehealth appointment (e.g., scheduling, system requirements, testing connections, appointment reminders, and log-on instructions) must be accessible.

### **Private Right of Action**

The NHC supports the important inclusion of a private right of action under Section 1557. Without this important tool, patients that are discriminated against are left without appropriate recourse. A private right of action will allow patients to receive redress for facing discrimination and hold those who discriminate responsible.

### **Additional Recommendations**

In addition to the above comments, the NHC has two additional recommendations for CMS.

We ask CMS to include caregivers as a group that must have meaningful access under the language access requirements specifically. Caregivers are often an important part of the care team, and we must assure that they have access to information about their loved one's health care.

Finally, we ask that CMS make the definition of sex consistent by using same definition for Medicaid and the Program for All-Inclusive Care for the Elderly (PACE). This proposed rule makes considerable progress in clarifying what discrimination on the basis of sex entails. It will help assure that patients are fully protected if the definitions are consistent and applied in all health care systems.

## **Value Assessment Methodologies**

The NHC appreciates that CMS is using the proposed rule to explore the civil rights implications of value assessment methodologies and value-based purchasing arrangements.

The NHC is committed to the promotion of high-value care and works to ensure that the cost of health care products and services align with value to the patient. The NHC recognizes patients as the source of authority on defining “value” in the context of the health care system, and therefore urges CMS to incorporate a patient-centric perspective in any efforts to eliminate discriminatory implications of value assessment. If value is defined from an appropriate patient perspective, it will better meet the needs of all patients.

It is also important that evidence about value should not come from comparative clinical effectiveness research that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill.

## **Implications of the Dobb’s Decision**

Thank you for requesting comment on any potential implications of the recent *Dobbs v. Jackson Women’s Health Organization* decision. This ruling has caused confusion about the role of the pharmacist in dispensing certain medications and threatened patient access to needed medications and care. Media reports<sup>123</sup> detail the experiences of women who have been denied prescriptions and refills of methotrexate, a medication that treats a variety of conditions such as rheumatoid arthritis, inflammatory bowel disease, psoriasis, and cancer. Some pharmacists are halting all prescriptions and refills because the medication can cause miscarriage and is an off-label treatment to end ectopic pregnancies. In some instances, it has been reported that women are being questioned about the purpose and intended use of certain prescription medications. This is an uncomfortable interaction for any patient to experience at the pharmacy counter, a location that is not completely private. We believe this is an example of gender-based discrimination. NHC is concerned that absent clarity about the role of the pharmacist and clarity on requirements to dispense medications, these interactions and denials could continue despite implementation of the final Section 1557 implementing rule. In light of the *Dobbs’* decision, we request HHS clearly delineate an example of these interactions in the final rule as potentially discriminatory action. We also request that HHS consider an expedited reporting and investigation process for complaints of this nature to facilitate timely access to prescription medications.

---

<sup>1</sup> <https://www.latimes.com/california/story/2022-07-11/post-roe-many-autoimmune-patients-lose-access-to-gold-standard-drug>

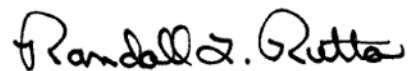
<sup>2</sup> <https://www.pharmacytimes.com/view/hhs-guidance-for-pharmacists-following-supreme-court-abortion-decision-creates-confusion>

<sup>3</sup> [https://www.nola.com/news/healthcare\\_hospitals/article\\_238af184-ff02-11ec-9bce-dfd660a21ce1.html](https://www.nola.com/news/healthcare_hospitals/article_238af184-ff02-11ec-9bce-dfd660a21ce1.html)

## Conclusion

The NHC appreciates the great work that has been done to restore and expand access to non-discriminatory health care for all patients. Please contact Eric Gascho, Senior Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable via e-mail at [egascho@nhcouncil.org](mailto:egascho@nhcouncil.org).

Sincerely,

A handwritten signature in black ink that reads "Randall L. Rutta". The signature is written in a cursive style with a large initial 'R' and a distinct 'L'.

Randall L. Rutta  
Chief Executive Officer