October 3, 2022

Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Melanie Fontes Rainer
Acting Director
Office for Civil Rights
U.S. Department of Health & Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Comments in Response to Proposed Rule Regarding Non-Discrimination in Health Care Programs and Activities

Dear Secretary Becerra, Administrator Brooks-LaSure, and Acting Director Fontes Rainer,

On behalf of OCHIN, we strongly support the U.S. Department of Health and Human Services (HHS or the Agency) proposed rule to strengthen non-discrimination protections in federal health care programs. OCHIN is a national, nonprofit community-based health IT innovation and research network that includes more than 1,000 community health care sites with 21,000 providers in 47 states, reaching more than 6 million patients. The OCHIN network is comprised of federally qualified health centers (FQHCs), rural health clinics (RHCs), Ryan White HIV/AIDS Program centers, school-based health clinics, corrections, local public health agencies, certified community behavioral health clinics (CCBHC), complex specialty mental health organizations, and critical access hospitals. OCHIN applauds the proposed changes in the rule that would comprehensively prohibit discrimination in a way that addresses health disparities, which are particularly stark for communities of Color, individuals with disabilities, women, LGBTQI+ communities, individuals with limited English proficiency, older adults, and children.

OCHIN Driving Equity and Innovation

For over 20 years, OCHIN has been an established leader in equitable health care innovation, and a trusted partner to a large and growing national provider network. Our network members serve patients who are clinically complex and must overcome significant societal risks (referred to as social determinants of health (SDOH)). Almost 45% of network patients are covered by Medicaid and 32% are uninsured. OCHIN’s members serve rural, partially rural, urban, and suburban communities and their patients represent a richly diverse demographic tapestry. Nearly 30% of the network’s patients are best served in a language other than English, over 40% are Persons of Color and nearly 26% identify as Hispanic/Latino. In addition, over 52% are women, 23% are children, almost 11% are seniors and 2% are veterans. The network also includes people living with disabilities and members of the LGBTQ+ community.
Recommendation Highlights

To address both structural inequality and individual discriminatory actions in federal health care programs, OCHIN offers the following summary recommendations with additional comments in the attached appendix:

OCHIN strongly supports:

- Clarifying and strengthening protections to ensure equal access to health programs or activities without discrimination on the basis of sex which includes prohibiting discrimination on the basis of pregnancy or related conditions, including pregnancy termination.
- Explicitly prohibiting the denial or limitation of health services sought for the purpose of gender-affirming care that would otherwise be provided for other purposes if the denial or limitation is based on a patient’s sex assigned at birth, gender identity, or gender otherwise recorded.
- Ensuring meaningful access to health care for services for individuals who prefer a language other than English; and, consistent with the foregoing, OCHIN urges modification of the proposed rule so that in those instances that real-time machine translation services are utilized, they are not subject to delay in order to adhere to the proposed intervening human reviewer requirement.
- Establishing clear expectations for the use of telehealth in a manner that does not discriminate by requiring the provision of appropriate auxiliary aids and services for individuals with disabilities and language assistance services for limited English proficient individuals.
- Strengthening protections for individuals with disabilities by clarifying these protections extend to their companions, if the latter have disabilities, and establishing national accessibility standards for information and communication technology with adequate time to employ change management, workflow changes, and training to update.
- Clarifying the scope of non-discrimination in health insurance and other health-related coverage to include important elements such as benefit design, cancellations, renewals, cost sharing, as well as other provisions contained in the proposed rule.
- Prohibiting discrimination related to marital, parental, or family status as these have not been included in the prior final rule (but are similar to HHS Title IX regulations).
- Clarifying that the non-discrimination prohibitions extend to the Medicare Part B program.

Finally, OCHIN urges the Agency to carefully consider the following two additional provisions of the proposed rule:

- **Data Collection.** In lieu of specifying the data collection measures such as race, ethnicity, language, sex, gender identity, sexual orientation, disability, and age, for example, the Agency seeks comment on whether existing data collection systems are sufficient data sources.

  OCHIN encourages the Agency to utilize existing data collection systems to minimize provider burden. In addition, OCHIN urges HHS to work across all agencies, including OCR, to establish uniform data standards utilizing national digital data standards and technical guides in order to reduce collection and reporting duplication and differences that are burdensome on patients and providers in underserved communities, in particular, and divert scarce resources from the delivery of care. A critical starting point would be the Office of the National Coordinator for Health Information Technology and the U.S. Core Data for Interoperability (USCDI).
Clinical Algorithms in Decision-Making. The Agency proposes a new provision that prohibits discrimination against any individual on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in decision-making.

OCHIN strongly supports the intent of this proposed provision, but urges the Agency to convene stakeholders such as OCHIN with decades of experience driving equity leveraging health information technology as well as federal agencies (such as the Food and Drug Administration, the National Institute for Standards and Technology, and the Federal Trade Commission) to better define the full-range of clinical algorithms and applications that are covered and the respective roles and accountability of developers, adopters/implementers, and end-users.

- OCHIN agrees that there is an immediate need to address structural inequity systematically caused by clinical algorithms.
- However, there is a regulatory and oversight vacuum that must be addressed as well as individual practice. The proposed rule falls far too short by only addressing the latter.
- The Agency has not ensured that a clear and comprehensive framework exists to differentiate among the continuum of clinical algorithms that can be embedded in systems without the knowledge or awareness of end-users to those that are developed, designed, and validated by end-users also acting as the developer.
- The proposed rule creates perverse incentives by shifting regulatory oversight of such tools from existing regulatory agencies and accountability from developers to end-users who, for a range of clinical algorithms, will not have the data or information needed to adequately evaluate this issue.
- This imposition of strict liability on end-users will chill adoption and use of all tools that are critical to assist with population health and addressing patient needs among underserved communities.
- In fact, it is very likely to drive structural inequity as only the most resource rich health systems and providers will be well-positioned to assume this risk while providers in underserved communities will not.

We appreciate the opportunity to comment and welcome working with the Agency to address a full range of technology and data issues given OCHIN’s over 20 years of experience advancing innovation and equity in underinvested communities facing persistent structural inequality. Please contact me at stollj@ochin.org as we welcome supporting your efforts to improve healthcare for all.

Sincerely,

Jennifer Stoll
Executive Vice President
External Affairs
Specific Applications to Health Programs and Activities

Equal Program Access on the Basis of Sex
The Agency provides that covered entities must provide individuals equal access to the covered entity’s health programs or activities without discrimination on the basis of sex including discrimination on the basis of pregnancy or related conditions, including “pregnancy termination.”

Furthermore, the Agency would explicitly prohibit covered entities from denying or limiting health services sought for the purpose of gender-affirming care that the covered entity would provide to a person for other purposes if the denial or limitation is based on a patient’s sex assigned at birth, gender identity, or gender otherwise recorded.

OCHIN: OCHIN strongly supports these proposed clarifications.

Meaningful Access for Individuals Using a Language Other than English (referred to as Limited English Proficient (LEP)) Individuals
The Agency proposes to:

- Require a covered entity to take reasonable steps to provide meaningful access to each LEP individual “eligible to be served or likely to be encountered.” The Agency proposes to revise this language slightly to include individuals likely to be “directly affected” rather than “encountered,” making it consistent with the 2003 HHS LEP Guidance and OCR resolution agreements.
- Require language assistance services to be provided free of charge, be accurate and timely, and protect the privacy and independent decision-making ability of an LEP individual. This provision is not different from the 2016 or 2020 rules.
- Require covered entities that use machine translation to have translated materials reviewed by a qualified human translator when the underlying text is critical to the rights, benefits, or meaningful access of an LEP individual; when accuracy is essential; or when the source documents or materials contain complex, non-literal, or technical language.

OCHIN: OCHIN strongly supports these provisions. OCHIN urges the Agency to ensure a wide-range of approaches — to in-person translators, virtual translators, and machine translators — can be used to meet these obligations in underserved communities. However, OCHIN urges the Agency to modify the proposed rule to clarify that real-time translation utilizing machine translation is not subject to the human translator requirement. With respect to machine translation, the Agency should recognize that its proposed requirements could chill the use of machine translation tools across covered entities, ultimately harming patient care, increasing healthcare costs, and adding to provider burdens. We strongly urge the Agency to
consider the wide benefits that machine translation tools provide today across healthcare contexts, particularly in real-time communications, and to clarify that a mandate for review by a human interpreter does not apply to real-time communications (whether in-person or via video); and that compliance analyses will weigh the net impacts of removing machine translation tools from the care continuum entirely in assessing the reasonableness of a covered entity’s activities in using such machine translation tools under its proposed factors.

**Effective Communication for Individuals with Disabilities**
The Agency currently requires a covered entity to take appropriate steps to ensure that communications with individuals with disabilities, and companions with disabilities, are as effective as communications with individuals without disabilities in its health programs and activities. This incorporates standards from the Americans with Disabilities Act (ADA) – includes “companions” to codify the Department’s longstanding position that a covered entity’s obligation to ensure effective communication extends not just to individuals with disabilities but to companions as well, if they are individuals with disabilities.

**OCHIN:** OCHIN strongly supports this provision.

**Accessibility of Information and Communication Technology for Individuals with Disabilities**
The Agency requires covered entities to ensure that their health programs and activities provided through Information and Communication Technology (ICT) are accessible to individuals with disabilities, unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities.

Many covered entities currently rely on Section 508 standards promulgated by the Access Board or Web Content Accessibility Guidelines (WCAG) developed through the Worldwide Web Consortium’s (W3C) Web Accessibility Initiative to ensure that their ICT is accessible to individuals with disabilities.

**OCHIN:** OCHIN strongly supports establishing a national standard while ensuring the regulatory language is clear that it applies to updated standard with adequate time, at least 6 months, to upgrade to newest version to account for workflow, technical changes, and training and education. Covered entities that are in compliance with the standard should be deemed compliant with the rule.

OCHIN agrees that it is extremely important for health centers to adhere to national standards. Currently, systems deploying WCAG 2.0, 2.1 standards and Section 508 web design, utilize information and communication technology (ICT) accessibility standards that are understood, implemented, and used by health centers. WACG 2.0 should be required at a minimum, as it is the basis for Section 508 web design. As of 2012, WACG 2.0 is an international standard (ISO/IEC 40500:2012) utilized for accessibility across the
world, resulting in ease of use and familiarity for individuals who need such accessibility functionality. Aside from these well-known accessibility standards, health centers that use certified electronic health record technologies (CEHRT) meet requirements for patient access to respective electronic health records as these programs utilize WACG 2.0 for their accessibility. Similarly, health centers are also using the same accessibility standards for patient portals to access their health information online.

OCHIN urges the Agency to not require the most recently published standard for accessibility immediately upon publication. Many providers in underserved communities must account for workforce shortages, and continually evolving standards and technology. It is crucial that safe harbor provisions be offered to health centers who are compliant with current standards and that adequate time is provided for adoption and integration of the new versions of the standard that accounts for testing, workflow re-design, and testing.

Nondiscrimination Provisions

**Discrimination Prohibited**
The Agency proposes a clarification that discrimination on the basis of sex includes discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity.

**OCHIN:** OCHIN strongly supports this clarification of the definition of discrimination consistent with the statute. The adverse health consequences of discriminatory practices for LGBTQ+ patients are well-documented and have long-term consequences for patients, their families, and communities. It is also essential to provide clarification of the scope of this regulation for individuals who are pregnant or with a related condition.

**Nondiscrimination on the basis of association**
The Agency offers a proposed clarification that covered entities must not exclude from participation in, deny the benefits of, or otherwise discriminate against an individual in its health programs and activities on the basis of the respective race, color, national origin, sex, age, or disability of the individual and another person with whom the individual has a relationship or association.

**OCHIN:** OCHIN strongly supports this provision.

**Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage**
The Agency currently prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in the provision or administration of health insurance coverage and other health-related coverage. The proposed rule would also prohibit discrimination in:
• marketing practices or benefit designs,
• denying, cancelling, limiting, or refusing to issue or renew health insurance coverage or other health-related coverage, or denying or limiting coverage of a claim, or imposing additional cost sharing or other limitations or restrictions on coverage
• denying or limiting coverage, denying, or limiting coverage of a claim, or imposing additional cost sharing or other limitations or restrictions on coverage to an individual based upon the individual’s sex at birth, gender identity, or gender otherwise recorded

All of these protections specifically apply to health-related coverage offered through the Exchanges, Medicare Part B and Medicaid.

**OCHIN:** OCHIN strongly supports this provision. Nearly 50 percent of OCHIN members are covered under Medicaid while the remaining or either uninsured or covered under other federal and state health care programs. It is critical that patients, particularly those in rural and other underserved communities have equal access to coverage and health care services regardless of health care program.

**Nondiscrimination in the Delivery of Health Programs and Activities Through Telehealth Services**
The Agency proposed to clarify that covered entities are required to provide telehealth services in a manner that does not discriminate on a protected basis, including through the accessibility of telehealth platforms and by providing effective communication for individuals with disabilities through the provision of appropriate auxiliary aids and services and language assistance services for LEP individuals. Such services would include communications about the availability of telehealth services, the process for scheduling telehealth appointments, (including the process for accessing on-demand unscheduled telehealth calls), and the telehealth appointment itself.

**OCHIN:** OCHIN strongly supports the clarification that non-discrimination prohibition extends to telehealth. Telehealth provides is a critical modality for patients who face structural barriers to access. An analysis of 2020 OCHIN network California members found that 46% of the telehealth encounters were delivered in a language other than English, with 3 out of 4 served in Spanish. The ability to access health care via telehealth is a vital modality to advance health equity and to remedy longstanding health disparities. In addition to this important provision, it is critical that federal and state health care programs, such as Medicare and Medicaid, continue to provide coverage for telehealth, including audio-only, to ensure medically complex patients facing significant social determinants of health are able to access telehealth.

**Prohibition on Sex Discrimination Related to Marital, Parental, or Family Status**
The Agency proposes in to provide that covered entities are prohibited from discriminating on the basis of sex in their health programs and activities with respect to an individual’s marital, parental, or family status. The 2016 and 2020 Final Rules did not include a similar provision. This is not a new concept, however, as it is similar to the Department’s Title IX regulation. The Agency
is also taking into consideration whether to include discrimination on the basis of pregnancy-related conditions.

**OCHIN:** OCHIN strongly supports the extension of protections which should include pregnancy-related conditions as well.

**Medicare Part B Meets the Definition of Federal Financial Assistance**

The Agency proposes to clarify that Medicare Part B meets the definition of Federal Financial Assistance, meaning that all the protections against discrimination include patients who have Medicare Part B.

**OCHIN:** OCHIN strongly supports this clarification and appreciates that these protections extend to beneficiaries of Medicare Part B. The clarification will eliminate confusion for older adults and people with disabilities and help ensure that people with Medicare have the same protections and rights regardless of the Medicare provider they choose, the Medicare-covered service they are receiving, or whether they are in Original Medicare or Medicare Advantage. Bringing all Medicare providers under this rule will also help increase access to quality health care for underserved communities who face the most discrimination and barriers, as many Medicare providers like federally qualified health centers (FQHCs) serve people with other forms of insurance.

**Procedures, Process, Staff, Notifications**

**Designation and Responsibilities of a Section Non-Discrimination Coordinator**

The Agency proposes to permit covered entities to, as appropriate, assign one or more designees to carry out some of the responsibilities of the Section 1557 Coordinator. The 2016 Rule did not include this provision.

**OCHIN:** OCHIN supports this new provision and appreciates the Agency’s decision to allow health centers the flexibility of how to assign responsibilities among staff.

**Policy & Procedures**

The Agency would require each covered entity, in its health programs and activities, to adopt and implement “Section 1557 Policies and Procedures.” This includes:

- a nondiscrimination policy,
- civil rights grievance procedures (for covered entities employing 15 or more persons). (This is similar to the 2016 Rule, except that we propose to include a record retention requirement.)
- language access procedures,
- auxiliary aids and services procedures, and
- procedures for reasonable modifications for individuals with disabilities.
The Agency would require covered entities to train relevant employees whose roles are affected by material changes to the covered entity’s Section 1557 Policies and Procedures. The training component is a new requirement, however many covered entities already have civil rights trainings for their employees that could be modified to comply with this proposed provision.

**OCHIN:** OCHIN supports this provision where it can be included in annual staff training. OCHIN strongly urges the Agency to provide model resources and templates to reduce the cost and complexity of developing and updating these materials for providers in underserved communities that have to re-direct funds needed for patient care to meet administrative compliance requirements.

**Notice of Nondiscrimination**

Rather than requiring entities to include the notice in “significant” communications, the Agency suggests covered entities provide the notice on an annual basis and upon request. Similar to the 2016 rule, the Agency suggests a notice also be placed at a conspicuous location on the covered entity’s health program or activity website, if it has one, and in clear and prominent physical locations where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice.

**OCHIN:** OCHIN strongly supports this clarification by the Agency to reduce administrative burden and costs.

**Notice of Availability of Language Assistance Services and Auxiliary Aids and Services**

The Agency requires a covered entity to provide a notice that, at minimum, states that the covered entity provides language assistance services and appropriate auxiliary aids and services free of charge in its health programs and activities, when necessary for compliance with Section 1557 or this part. This notice must be provided to participants, beneficiaries, enrollees, and applicants of the covered entity’s health program or activity, and members of the public. Notice can be provided through written translations or recorded audio or video clips. The Notice of Availability has to be provided in English and at least the 15 most common languages spoken by LEP individuals of the relevant state or states, and in alternate formats for individuals with disabilities who request auxiliary aids and services to ensure effective communications. Furthermore, they need to be provided with the following documents:

- the notice of nondiscrimination required by this proposed rule;
- the notice of privacy practices required by the implementing regulations for the Health Insurance Portability and Accountability Act of 1996 (HIPAA) at 45 CFR 164.520;
- application and intake forms;
- notices of denial or termination of eligibility, benefits, or services, including Explanations of Benefits (EOBs), and notices of appeal and grievance rights;
• communications related to a person’s rights, eligibility, benefits, or services that require or request a response from a participant, beneficiary, enrollee, or applicant;
• communications related to a public health emergency;
• consent forms and instructions related to medical procedures or operations, medical power of attorney, or living will (with an option of providing only one notice for all documents bundled together);
• discharge papers;
• complaint forms; and
• patient and member handbooks.

However, entities can give individuals the option to opt-out of receipt of the notice of availability once a year and documents the individual’s primary language and provides the individual all the necessary auxiliary aids and services, and communications in that primary language.

**OCHIN:** OCHIN supports this provision and the option to opt-out of notice annually while documenting a patient’s primary language and while providing necessary tools and communication to ensure access.

**Data Collection**

Rather than codifying a specific set of data collection measures (race, ethnicity, language, sex, gender, gender identity, sexual orientation, disability, and age) within this rulemaking, the Agency proposes to use existing data collection sources from federal programs. The Agency seeks comments on this approach, including whether covered entities, as recipients of Federal financial assistance include a variety of entities such as FQHCs, are already collecting disaggregated demographic data in their health programs and activities and, if so, for which categories of data, through what systems, and at what cost.

**OCHIN:** OCHIN encourages the Agency to utilize existing data collection systems to minimize provider burden. However, OCHIN also urges HHS to work across all of its agencies, including OCR, to establish uniform data standards utilizing national digital data standards and technical guides in order to reduce collection and reporting duplication and differences that are burdensome on patients and providers in underserved communities, in particular, and divert scarce resources from the delivery of care. A critical starting point would be the Office of the National Coordinator for Health Information Technology and the U.S. Core Data for Interoperability.

**Use of Clinical Algorithms in Decision-Making**

The Agency proposes to prohibit a covered entity from discriminating against any individual on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decision-making.
OCHIN: OCHIN strongly supports the Agency’s goal of addressing discriminatory clinical algorithms. We urge the Agency to partner with stakeholders such as OCHIN with extensive experience at the intersection of equity and health information technology and innovation within the safety net, other clinician innovators and health systems and other federal agencies to provide a clear regulatory framework for the respective obligations, accountability, and roles of developers, adopters/implementers, and end-users of clinical algorithms.

A critical first step for the Agency and stakeholders will be to clarify the scope of this proposed provision with regard to methods, modality, intended use, and whether end-users are also the developer, designer, and validator before finalizing this provision. Assigning accountability and liability among individuals and entities in the best relative position to identify discriminatory harm and best positioned to remedy it is crucial to avoid widespread discrimination.

Further, given the current scope, it is not possible for the providers and other regulated entities to know what is required in order to comply. The definition of clinical algorithm in this proposed rule could apply to a wide variety of algorithms, from rules-based flow-chart algorithms to machine-learning systems. Use of basic clinical calculations that are automated through algorithms can be considered standard of care and clinicians typically understand the inputs, the logic and clinical evidence that underlies the algorithm. Where clinicians utilizing these types of algorithms clearly understand the inputs and why the algorithm produces the output, clinician accountability would be appropriate.

However, this is materially different than algorithms embedded in black box systems that clinicians would not be in a position to test or even have the resources or training to evaluate even if the underlying clinical basis for the output was described. Clinicians may not have information regarding the data used to train the advanced algorithmic systems (including those utilizing machine learning), and whether that data accurately represents the populations in which it is being used and may also have no reason to understand or know the algorithm’s logic, or, most importantly, when an algorithmic error has occurred, or bias has been introduced.

There is a role for current regulatory agencies (such as the Food and Drug Administration and the Federal Trade Commission), frameworks and standards offered by the National Institute of Standards and Technology, as well as emerging consensus frameworks detailed below that address personnel, process, procedure, validation, and continuous monitoring to ensure well-understood requirements for both developers and end-users of such tools are established. The proposal by Agency contemplates a level of clinician understanding that is simply not possible with many of these clinical algorithms that utilize machine learning, for example.

We urge the Agency to partner with stakeholders to advance appropriate processes that will identify, address, and mitigate harmful bias in clinical algorithms through existing regulatory and other federal agency processes or consensus driven frameworks such as:

- The Health AI Partnership launched in December 2021 focused on decentralizing the high concentration of technology and regulatory expertise from some leading health systems across the U.S. and using it to develop guidelines to help other organizations make smarter decisions.
Brigham and Women’s Hospital’s partnership with the American Medical Association and the Joint Commission on a quality and safety peer network to exchange information on where they are finding discrimination or bias that affect patient safety and how to solve them.

The National Institutes of Health (NIH) Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM AHEAD) of which OCHIN is a participant to support inclusive teams involved in ideation, design, development, validation and implementation that will surface and address both risk of and actual bias along the life cycle of clinical algorithms while promoting AI systems that advance equity in health care.

The stakeholders driven open source publication series related to Surfacing Best Practices for AI Software Development and Integration in Healthcare.

The FDA Collaborative Communities Foundational Considerations for Artificial Intelligence Workgroup (FPOAI).

Fundamentally, the proposed rule creates perverse incentives and misalignment of risk and benefit. The end-user will often have the least information to take steps to mitigate bias and will not be in a position to validate, but in some instances, may. Those best positioned to mitigate and who may derive the most economic benefit should have accountability for validating clinical algorithms and ensuring they are not biased, not only as designed and developed, but as implemented as intended.

To avoid creating structural inequality among providers that are least resourced and those who have substantially more resources, we urge the Agency to consider the impact of the proposed rule on covered entities’ practical ability to use clinical algorithms, particularly for frontline safety net covered entities with limited resources.

We urge further consultation with and outreach to the FDA, NIH, NIST, FTC and stakeholders to develop a framework of the state of clinical algorithms and deployments, including technical and legal realities of clinical algorithms life cycles in varied settings, particularly in underinvested communities where the providers are proving access to the most diverse patient population.