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October 3, 2022

Melanie Fontes Rainer  
Director, Office for Civil Rights (OCR)  
U.S. Department of Health and Human Services  
Attention: 1557 NPRM (RIN 0945-AA17)  
Hubert H. Humphrey Building, Room 509F  
200 Independence Avenue SW  
Washington, DC 20201

**Re: Nondiscrimination in Health Programs and Activities [[Docket ID: HHS-OS-2022-0012](#)]**

Director Rainer,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide feedback to HHS OCR's Nondiscrimination in Health Programs and Activities proposed rule. NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a \$67 billion healthcare marketplace, employ 215,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

**Equal Program Access on the Basis of Sex (§ 92.206)**

In the proposed rule, HHS OCR proposes to include a section clarifying covered entities' obligation to ensure equal access to their health programs and activities without discrimination on the basis of sex, including pregnancy, sexual orientation, gender identity, and sex characteristics. As stated in the proposed rule, this provision primarily relates to covered entities that are directly engaged in the provision of health care services. The proposed rule explicitly includes pharmacies as covered entities.

The proposed rule further states that if the HHS OCR Director finds that a covered entity has discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of Section 1557 or this part, such covered entity must take such remedial action as the Director may require to overcome the effects of the discrimination under Section 92.6 of the proposed rule. Further, Section 92.301 of the proposed rule states that enforcement mechanisms available for and provided under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, and the Age

Discrimination Act of 1975 shall apply for purposes of Section 1557 as implemented by this propose rule.

**NCPA asks HHS OCR to provide assurances that pharmacists can use reasonable clinical judgement to treat patients within their scope of practice, and not be subject to additional administrative burden and legal liability.**

### **Abortion Neutrality Provision**

The proposed rule states that HHS OCR's view is that Section 1557 does not require the Department to incorporate the language of Title IX's abortion neutrality provision<sup>1</sup> into its Section 1557 regulation. HHS OCR further notes that there are several other statutory and regulatory provisions related to the provision of abortions that may apply to an entity covered by Section 1557, and OCR will apply such provisions consistent with the law. While HHS OCR also notes that though Congress did not require the Department to incorporate the language of Title IX abortion-neutrality provision in its Section 1557 regulations, it is seeking comment on this approach and on other possible readings of the Title IX abortion-neutrality provision, as well as whether the Department should align its Title IX regulation regarding the abortion neutrality provision of Title IX with the 2000 "Common Rule" version of that regulatory provision that more than 20 agencies have long adopted.

NCPA is concerned about state laws that limit patients' access to medically necessary medications and impede physicians and pharmacists from using their professional judgment. Following the U.S. Supreme Court *Dobbs v. Jackson Women's Health Organization* decision, physicians, pharmacists, and other health care professionals face a confusing legal landscape due to state laws' significant criminal and civil penalties, lack of clarity, confusing language, and unknown implementation by regulatory and enforcement bodies. This includes many questions about how broadly state laws will be interpreted and the impact of these actions on pharmacists' ability to serve the needs of their patients. Pharmacists need clear guidance from HHS OCR to support the prescribing and dispensing of medically necessary medications that may be affected by this new legal and regulatory paradigm. Without such guidance, we are deeply concerned that our patients will lose access to care and suffer irreparable harm.

In the wake of the *Dobbs* decision, over half of U.S. states have severely restricted or are expected to soon restrict access to abortion services, including medications that induce abortions. In many states, these laws prohibit prescribing and dispensing an "abortion-inducing drug," or contain other comparable terms. This language is vague, and it is unclear whether it prohibits certain medications only when prescribed to induce abortion or whether a medication is prohibited entirely if it has the potential to induce abortion regardless of the condition for which it was prescribed. Namely, as stated above, methotrexate can be used off-label for the termination of intrauterine pregnancy and is also approved and used off-label for numerous

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<sup>1</sup> 20 U.S.C. 1688: "Nothing in this chapter shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion. Nothing in this section shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion."

indications such as cancer and ectopic pregnancy along with being commonly prescribed as the first-line treatment of inflammatory diseases such as arthritis. Similarly, mifepristone is indicated for the termination of pregnancy but is also prescribed in a medical emergency to treat ectopic pregnancy, preeclampsia, and other emergent medical presentations during labor and delivery and for the medical management of a miscarriage.

Patients who rely on these medications for reasons unrelated to pregnancy termination report new challenges in accessing these and other medications, and it is placing our patients' health at risk. Many health care professionals, including pharmacists, are uncertain of their legal liability related to prescribing and/or dispensing these medications regardless of whether they are being used for an abortion or another indication.

Without access to medications proven to be safe and effective, our patients' health is at risk. As pharmacists, we view patient wellbeing as paramount and are deeply troubled that continuity of care is being disrupted. **We call on HHS OCR to ensure through this regulation that patient care is not disrupted and that pharmacists shall be free to continue to practice without fear of professional sanction or liability. We strongly urge HHS OCR to act to help ensure that our patients retain continuity of care and that our members clearly understand their legal obligations.**

#### **Notification of Views Regarding Application of Federal Conscience and Religious Freedom Laws (§92.302)**

Additionally, HHS OCR proposes to adopt a process by which recipients of federal financial assistance may inform the Department of their views that the application of a specific provision or provisions of this part to them would violate Federal conscience or religious freedom laws, so that the Department may, as appropriate, make a determination that recipients are exempt from, or entitled to a modification of the application of, a provision or provisions of this proposed rule. While not incorporating the Title IX religious exception, HHS OCR stated that it is fully committed to respecting conscience and religious freedom laws when applying this rule. HHS OCR sought comment on this approach.

**NCPA welcomes that HHS OCR is proposing to recognize recipients, including pharmacists, may have a right to object to specific provisions in the proposed rule since they would violate Federal conscience or religious freedom laws. That said, NCPA requests clarity that HHS OCR would allow pharmacists to not dispense certain prescriptions for reasons of religion or conscience, if they are doing so within their scope of practice, and that they give affected patients information on where to obtain these medications. NCPA supports such a right for pharmacists without requiring pharmacists to inform HHS OCR that they are exercising such right, and without requiring HHS OCR to make a determination that recipients are exempt from, or entitled to a modification of the application of, a provision or provisions of this proposed rule. NCPA believes that additional stipulations on pharmacists' right to object based on conscience and religious grounds would infringe on that right and add undue burden to the practice of pharmacy.**

#### **Section 1557 Coordinator**

Under the proposed rule, a covered entity that employs fifteen or more persons must designate and authorize at least one employee as a "Section 1557 Coordinator" to coordinate the covered

entity's compliance with its responsibilities under Section 1557 and the proposed rule in its health programs and activities, including the investigation of any grievance communicated to it alleging noncompliance with Section 1557 or the proposed rule or alleging any action that would be prohibited by Section 1557 or this proposed rule. According to the proposed rule, responsibilities of this Section 1557 Coordinator include: (1) receiving, reviewing, and processing grievances, (2) coordinating the covered entity's recordkeeping requirements; (3) coordinating effective implementation of the covered entity's language access procedures; (4) coordinating effective implementation of the covered entity's effective communication procedures; (5) coordinating effective implementation of the covered entity's reasonable modification procedures; and (6) coordinating training of relevant employees, including maintaining documentation.

HHS OCR seeks comment on this requirement, including whether OCR should require covered entities with fewer than 15 employees to designate a Section 1557 Coordinator and, if so, whether there should be a requisite number of employees or whether all covered entities should be required to designate a Section 1557 Coordinator.

**NCPA opposes the designation of a Section 1557 Coordinator in its entirety. In 2021, independent pharmacy owners on average employed 12.3 full and part time workers.<sup>2</sup> However, NCPA opposes OCR requiring any entities, regardless of number of employees, to designate a Coordinator. Such a coordinator would greatly increase administrative burden to community pharmacies with greater than 15 employees, and we are also concerned from its comment request that HHS OCR would expand the Coordinator role to our members with fewer than 15 employees as well.** We agree with HHS OCR's original reasoning in 2020, as stated in the proposed rule, where HHS OCR repealed the requirement for each covered entity with 15 or more employees to designate a Section 1557 Coordinator or "designated employee," reasoning that to the extent that the implementing regulations for the referenced statutes "have responsible employee and grievance procedures, they are sufficient for enforcement of Section 1557."<sup>3</sup>

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<sup>2</sup> 2022 *NCPA Digest*, page 9, Table 4.

<sup>3</sup> See proposed rule, at 47846.

**Conclusion**

NCPA thanks HHS OCR for the opportunity to provide feedback, and we stand ready to work with HHS OCR to offer possible solutions and ideas.

Should you have any questions or concerns, please feel free to contact me at [steve.postal@ncpa.org](mailto:steve.postal@ncpa.org) or (703) 600-1178.

Sincerely,

A handwritten signature in black ink, appearing to read 'Steve Postal', with a long horizontal line extending to the right.

Steve Postal, JD  
Director, Policy & Regulatory Affairs  
National Community Pharmacists Association