

October 28, 2021

Lisa J. Pino
Director
Office for Civil Rights
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

Rochelle P. Walensky, MD, MPH
Director
U.S. Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Re: Preventing Inappropriate Use of Patient Protected Medical Information in the Vaccination Process

Dear Directors Pino and Walensky:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to encourage the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) and the U.S. Centers for Disease Control and Prevention (CDC) to **prohibit the use of patient/customer information collected by retail pharmacies for COVID-19 vaccination scheduling and/or the vaccine administration process for commercial marketing or future patient recruiting purposes, especially any targeting based on medical history or conditions.** In addition, **the AMA firmly opposes the sale or transfer of medical history data and contact information accumulated through the scheduling or provision of government-funded vaccinations to third parties for use in marketing or advertising.**

In early 2021, the HHS OCR notified the public that as a matter of enforcement discretion, it will not impose penalties for noncompliance with regulatory requirements under the HIPAA Rules against covered health care providers or their business associates in connection with the good faith use of online or web-based scheduling applications for the scheduling of individual appointments for COVID-19 vaccinations during the COVID-19 nationwide public health emergency (PHE).¹ This Notification of Enforcement Discretion was effective immediately, but with a retroactive effective date of December 11, 2020, and will remain in effect until the Secretary of HHS determines that the PHE no longer exists, or upon the expiration date of the PHE, including any extensions, whichever occurs first.²

According to the CDC, as of October 6, 2021, more than 141 million COVID-19 vaccine doses have been administered and reported by retail pharmacies across programs in the U.S., which includes eight million doses administered onsite to long-term care facilities in the early days of the vaccination program.³ While we acknowledge and appreciate that retail pharmacies have played a critical role in expanding access to COVID-19 vaccination, **we are concerned that some larger retail pharmacies are collecting a significant amount of medical history and contact information from patients seeking to schedule**

¹ During the COVID-19 national emergency, which also constitutes a nationwide [PHE], certain covered health care providers, including some large pharmacy chains and public health authorities, or their business associates acting for or on behalf of such providers, may choose to use online or web-based scheduling applications (collectively, "WBSAs") for the limited purpose of scheduling individual appointments for COVID-19 vaccination. <https://www.federalregister.gov/documents/2021/02/24/2021-03348/enforcement-discretion-regarding-online-or-web-based-scheduling-applications-for-the-scheduling-of>

² <https://www.federalregister.gov/documents/2021/02/24/2021-03348/enforcement-discretion-regarding-online-or-web-based-scheduling-applications-for-the-scheduling-of>.

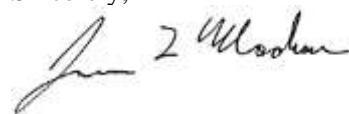
³ <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html>.

COVID-19 vaccinations, sometimes even for those merely seeking to see if an appointment is available. We are equally concerned that some larger retail pharmacy chains may see this as an opportunity to recruit patients to utilize their retail health clinics for routine visits in competition with a patient's medical home.^{4,5,6} Providers may be leveraging OCR's notice of enforcement discretion around online scheduling to collect and utilize data in this way even if the individual did not schedule their appointment online, as pharmacies tend to collect information on paper for individuals without Internet access, individuals who neglect to complete the pharmacy's requisite online forms in advance, and individuals who walk-in for COVID-19 vaccination without a previously scheduled appointment. We also have significant concerns regarding scheduling assistant websites or private providers asking about various medical conditions to assess eligibility priority and then retain the information. Unchecked data collection, sharing, and processing amplifies discrimination based on race, gender, sexual orientation, ability, age, financial status, and other group membership.⁷ It can lead to the development of risk scores by a wide range of companies, including health insurers, yet most people are not even aware these scores exist. Failing to address such misuse of data will contribute to declining levels of trust in our nation's public health agencies and infrastructure.⁸

The CDC has issued guidance to providers titled, *Use of Vaccine Recipient Data for Commercial Marketing Purposes Prohibited*, stating that "providers are prohibited from using or disclosing data collected from vaccine recipients for and through the CDC COVID-19 Vaccination Program for commercial marketing purposes or for any other purpose not allowed under this updated provision of the COVID-19 Vaccination Provider Agreement."⁹ We believe that because the guidance also states that, "[t]his prohibition is not intended to limit communications by health care providers to vaccine recipients with whom the provider has an existing relationship prior to contact about COVID-19 vaccination," some large retail pharmacies may not fully understand their obligations to protect the data collected from vaccine recipients and to not solicit *new* customers using the COVID-19 data they collect.¹⁰ Due to the volume of Americans who will be receiving their first COVID-19 vaccine doses or a booster shot in the coming months, we urge the Federal government to act swiftly in reiterating and clarifying necessary protections to ensure retail pharmacies do not, whether intentionally or inadvertently, misuse patient data they collect during the COVID-19 vaccination scheduling and/or the vaccine administration process.

We appreciate the opportunity to provide this information and look forward to continued conversations surrounding this important issue. If you have any questions, please contact Laura Hoffman, Assistant Director of Federal Affairs, at laura.hoffman@ama-assn.org.

Sincerely,



James L. Madara, MD

⁴ <https://www.politico.com/news/2021/04/03/pharmacy-covid-vaccine-customer-data-478977>.

⁵ <https://www.vox.com/recode/22310281/covid-vaccine-walgreens-cvs-rite-aid-walmart-data>.

⁶ <https://www.wsj.com/articles/cvs-walgreens-look-for-big-data-reward-from-covid-19-vaccinations-11614681180>.

⁷ *Big Data, a Tool for Inclusion or Exclusion?*, FTC, February 2016, available at <https://www.ftc.gov/system/files/documents/reports/big-data-tool-inclusion-or-exclusion-understanding-issues/160106big-data-rpt.pdf>.

⁸ https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2021/05/RWJF-Harvard-Report_FINAL-051321.pdf.

⁹ <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html>

¹⁰ <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html>.