

August 12, 2021

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*Submitted via email and via regulations.gov (Docket No. CDC-2021-0084)*

**Re: Critical Operational Recommendations for Additional COVID-19 Vaccine Doses at Pharmacies**

Dear Drs. Romero, Walensky and Woodcock, Secretary Becerra and Ms. Sackner-Bernstein,

The National Association of Chain Drug Stores (NACDS) thanks you for your ongoing leadership and partnership in the COVID-19 response. Since the emergence of COVID-19 in the U.S. in January of last year, community retail pharmacies and their staff have served in critical roles as part of the pandemic response. Frontline pharmacy staff have attended to Americans every day during this pandemic emergency by keeping pharmacies open to offer COVID-19 testing and vaccinations, dispense critical medications, and provide patient education and referrals. So far, pharmacies have administered more than 100 million COVID-19 vaccinations, including to adolescents, racial and ethnic minorities, and other vulnerable populations. Pharmacies have risen to this unprecedented challenge in an extraordinary way, conducting thousands of pop-up clinics, partnering with schools, employers, nursing homes, airlines and cruise lines, supporting mass vaccination sites, vaccinating teachers, reaching people who are homebound, and in so many other ways.

As the Advisory Committee on Immunization Practices (ACIP) considers the potential for additional COVID-19 vaccination doses or future boosters, and as FDA considers authorization of additional doses of COVID-19 shots for immunocompromised people, we appreciate the opportunity to provide the following comments and recommendations on behalf of our chain pharmacy members. Our recommendations seek to help ensure that the eligible public can efficiently and effectively access additional COVID-19 vaccination doses at their trusted and accessible retail pharmacies, should these doses be recommended by ACIP, the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA).

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering

innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit [nacds.org](https://nacds.org).

Retail pharmacies have been instrumental, along with many other vaccine providers, in expanding access and uptake of COVID-19 vaccinations thus far. Ensuring operational feasibility for pharmacies to deliver additional COVID-19 vaccination dose(s) will be critical to the nation's response efforts, especially as variants continue to emerge and as more information becomes available about the longevity of immunity following primary vaccination series. Further, any confusion or friction among the public, vaccine providers, jurisdictions, and other stakeholders could hinder getting vaccine doses to those who need them and delay and impede the nation's recovery from the pandemic, should additional COVID-19 vaccination doses be recommended.

We urge your consideration of the need for consistent, clear messaging to the public on when and how to seek additional doses of vaccine, and the need to align that messaging with operational realities and planning. Especially given the actions being considered by FDA and the ACIP this week, the need for consistent, clear messaging is evermore heightened. At this time, there are several unanswered questions regarding operational aspects of rolling out additional vaccine doses that should be addressed immediately. We strongly urge the Administration to work in lockstep with pharmacies to finalize operational details of this next phase of the vaccination campaign to help ensure a more seamless rollout to the public. With that context in mind, NACDS recommends the following to help ensure operational feasibility for individuals to access additional dose(s) or future booster(s) of COVID-19 vaccinations at pharmacies:

- 1.) CDC and ACIP should put forward clear and explicit eligibility criteria for immunocompromised individuals, and any other populations, for purposes of additional COVID-19 vaccination dose(s) or future booster(s). The definitions and eligibility criteria should ensure the ability for individuals to self-attest to their eligibility status (e.g. immunocompromised status), without requiring any verification or proof of their eligibility status (e.g. medical diagnosis). Updated clinical assessment tools for providers should be included in the initial messaging.**

Any ambiguity in eligibility criteria can result in doubt and confusion among both individuals who need extra protection from COVID-19 through additional doses *and* individuals who may not be recommended for additional doses, should ACIP recommend such. If ACIP's recommendation results in public doubt surrounding if they are in fact recommended to receive additional doses, not only could this delay getting doses swiftly to those who need them, but it may also overwhelm the healthcare system, especially vaccine providers, who will be tasked with helping the public make sense of an unclear recommendation. To best get additional vaccine doses to those who need them, ACIP and CDC should carefully ensure the recommended population is unequivocally outlined, without any latitude that could lead to ambiguity.

Importantly, ACIP and CDC should ensure the recommended population is defined clearly enough that individuals are able to self-attest to their eligibility status, without requiring any verification or proof of their eligibility status, which could undoubtedly lead to delays, barriers and obstacles for those who need additional vaccine doses and protection, should ACIP recommend such.

- 2.) CDC, ACIP, and HHS should expressly expect all jurisdictions to abide by and maintain the federal eligibility criteria and federal reporting requirements related to additional dose(s) or booster(s) of COVID-19 vaccines. CDC should express that jurisdictional awardee agreements, data use agreements,**

**funding awards, et al., require jurisdictions to abide by ACIP/CDC's recommended eligibility criteria for additional doses and CDC's federal reporting requirements.**

Specifically, jurisdictions, states, and counties should be discouraged from developing their own eligibility criteria for purposes of additional COVID-19 vaccinations and CDC, ACIP and HHS should require the eligibility criteria determined by ACIP and CDC is followed universally across all jurisdictions, states, and counties. For example, jurisdictions, states, and counties should not develop their own definitions of immunocompromised, nor create any other eligibility criteria, nor require any verification or proof of medical diagnosis to prove immunocompromised status, for example. As was observed with initial COVID-19 vaccination prioritization earlier this year, the lack of consistency across the nation led to public confusion, frustration and concerns regarding the fairness and equity of COVID-19 vaccination roll out and access.

Should the nation once again see local or state discrepancies with ACIP's recommendations, it is likely to create further preventable messaging inconsistencies and distrust among the very populations that critically need additional doses. For healthcare entities like community pharmacies and others operating regionally across several jurisdictions, or even nationally, any variation as to who is considered to be recommended for additional doses can create serious operational challenges, which can hinder our mutual goal of providing vaccine in an efficient and equitable manner, and defeating the ongoing pandemic. A unified, federal approach for additional COVID-19 doses or future boosters – without variation across jurisdictions – will allow for a more seamless roll out to the American people. A national framework that is fair and consistent will support the most effective and equitable deployment and uptake of additional doses across the country. National guidance should be consistently adopted, implemented and executed at all levels without variation.

With respect to data reporting, CDC and HHS should ensure no additional data reporting elements or burdens (at either the federal or the jurisdiction levels) are imposed on pharmacies or other vaccine providers with respect to additional COVID-19 dose(s) or booster(s). Also, the use of "unknown" for any additional data fields should be acceptable without repercussions. Additionally, CDC should consider the operational complexities associated with any change in dosing (volume, interval, etc.) for additional dose(s) or future booster(s) and seek to alleviate complexities whenever possible, especially with reporting requirements, including doses on-hand, inventory, and waste. Importantly, vaccine providers are already faced with many onerous, and at times, manual data reporting requirements and added burdens can undermine the goal to ensure efficient access to primary COVID-19 vaccinations and any recommended additional doses or boosters.

As such, it is critical for CDC to express that jurisdictional awardee agreements, data use agreements, funding awards, et al., expressly expect jurisdictions to abide by ACIP/CDC's recommended eligibility criteria for additional doses and CDC's federal reporting requirements, without any added requirements or nuances.

- 3.) Should only one product be recommended for additional dose(s) or booster(s), CDC and ACIP should provide flexibility for instances when the primary vaccination series/manufacturer is unknown or cannot be readily confirmed, in addition to supporting the ability for patients to self-attest to the manufacturer of their primary series, should the vaccine provider not have immediate access to that information.**

Requiring proof or confirmation of an individual's primary COVID-19 vaccination series may not always be feasible and should not be imposed as a barrier, which could impede access to additional doses for those

who are recommended to receive them. For example, should additional dose(s) or booster(s) be recommended for one manufacturer's product with consistency regarding the manufacture of the primary series, ACIP and CDC should recommend the manufacturer of additional dose(s) is consistent whenever possible, but with acceptable substitutions, for example, when the primary series cannot be confirmed.

Additionally, ACIP and CDC should support the ability for patients to self-attest to the manufacturer of their primary series, given that vaccine providers may not have access to that information. CDC should explicitly support and recognize vaccine providers that are acting in good faith with respect to maintaining consistency with the primary vaccine series and additional doses, should that be recommended.

**4.) CDC, ACIP, and HHS should expressly expect that prescribers across the nation align with ACIP eligibility criteria for additional doses or boosters of COVID-19 vaccinations authorized under EUAs.**

Over the last several weeks, prescribers across the nation are increasingly writing prescriptions for additional COVID-19 vaccine doses for their patients. Not only does this present a dilemma for vaccine providers, who must strictly adhere to the FDA's EUAs, it also creates tremendous frustration for members of the public who may believe they should receive additional COVID-19 doses when they have not yet been recommended. Therefore, CDC should clearly identify the role of prescribers, specifically if they have the flexibility to prescribe additional doses for patients they deem appropriate outside of ACIP's eligibility criteria. CDC should also clearly identify the role of vaccine providers, such as pharmacies, who may receive prescriptions for patients to receive additional doses who do not otherwise meet ACIP/CDC's eligibility criteria. Regardless of roles, NACDS strongly recommends CDC, ACIP and HHS expressly expect prescribers to adhere and align with ACIP eligibility criteria for additional doses or boosters of COVID-19 vaccinations authorized under EUAs.

Mitigating variations on eligibility criteria can help to ensure consistent and fair vaccine access in accordance with the highly rigorous and science-based processes of ACIP, CDC, and FDA. CDC should explicitly support and recognize vaccine providers that are acting in good faith with respect to following all existing and future ACIP/CDC recommendations for additional COVID-19 vaccine doses or boosters.

Managing public expectations on when and how to receive additional COVID-19 vaccine doses is critical to continuing a strong nation's vaccination campaign. Pharmacies continue to be a centerpiece of this response, yet as part of our ongoing partnership, we seek resolution on operational questions that are critical to public messaging on this new phase of the response. It will be critical that CDC and ACIP develop clear public messaging on the eligibility criteria, in addition to the specific vaccine products, doses, and intervals for additional dose(s) of COVID-19 vaccinations or booster(s) to help facilitate public understanding and continue to build vaccine confidence, should additional doses be recommended. We would like to discuss these recommendations at your earliest convenience. For any questions or further discussion, please contact NACDS' Sara Roszak, Vice President, Health and Wellness Strategy and Policy, at [sroszak@nacds.org](mailto:sroszak@nacds.org) or 703-837-4251.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven C. Anderson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Steven C. Anderson, FASAE, CAE, IOM  
President and Chief Executive Officer National Association of Chain Drug Stores