NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

August 26, 2021

Xavier Becerra
Secretary
Department of Health and Human Services (HHS)
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Chiquita Brooks-LaSure
Administrator
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7500 Security Boulevard
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Rochelle Walensky, MD, MPH
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Food and Drug Administration (FDA)
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The White House
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Grace Lee, MD, MPH
Chair
Advisory Committee on
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1600 Clifton Road, N.E.
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Cc: AJ Pearlman (HHS), Nikki Jo Romanik (CDC), Anita Patel (CDC), Jonathan Blum (CMS), Erin Richardson (CMS), Kyla Ellis (CMS)

Submitted via email and via regulations.gov (Docket No. CDC-2021-0089)

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

Dear Secretary Becerra, Administrator Brooks-LaSure, Drs. Lee, Walensky and Woodcock, and Ms. Sackner-Bernstein,

The National Association of Chain Drug Stores (NACDS) appreciates your ongoing leadership and partnership in the COVID-19 response. Since the emergence of COVID-19 early last year, community retail pharmacies and their dedicated staff have risen to the unprecedented challenge in extraordinary ways to support their communities. So far, pharmacies have administered more than 100 million COVID-19 vaccine doses, including to adolescents, racial and ethnic minorities, and other vulnerable populations.

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

Before sharing our current recommendations, we want to thank you for your leadership in swiftly and clearly addressing a concern we raised regarding off-label use of FDA-approved COVID-19 vaccines. The guidance provided to pharmacy partners this week was timely and appropriate, given FDA approval of the Pfizer-BioNTech COVID-19 vaccine for those 16 and older. NACDS would greatly appreciate ongoing communications from FDA and CDC that

discourage off-label use of COVID-19 vaccines by prescribers and states/jurisdictions given the complicated and tenuous situations that could occur for vaccine providers under such actions. Also related to the recent approval, in order to maintain public access, it is important that CMS and other payers continue to cover COVID-19 vaccines authorized via an Emergency Use Authorization (EUA), in addition to COVID-19 vaccines approved via a Biologics License Application (BLA), as mandated by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) and the Families First Coronavirus Response Act (FFCRA).

Along with other vaccine providers, retail pharmacies have been instrumental, in expanding access and uptake of COVID-19 vaccinations thus far. Therefore, ensuring operational feasibility for pharmacies to deliver COVID-19 vaccine booster doses will be critical to the nation's ongoing response efforts. Specifically, NACDS recommends the following to help ensure operational feasibility for individuals to access COVID-19 vaccine boosters at pharmacies:

1.) **A forthcoming booster recommendation should be unequivocally outlined by ACIP and CDC, without any latitude that could lead to ambiguity, and without additional complexities, requirements, or nuances from the state or local levels. Any upcoming recommendation determined by ACIP and CDC should explicitly support the ability for individuals to self-attest to their primary vaccination series (e.g., product, date of the second dose).**

   Specifically, NACDS strongly recommends that ACIP and CDC outline an explicit age (e.g., 18 years and older) and time interval (e.g., no sooner than 8 months from date of the second dose) in any forthcoming booster recommendation, without flexibility that could lead to public doubt and confusion regarding if someone may indeed benefit from a booster dose. Ensuring clarity around who is recommended to receive a COVID-19 booster dose is critical to getting boosters swiftly to those who need them, in addition to alleviating undue burdens on vaccine providers who will be tasked with helping the public determine if and when they may be recommended for a booster. Also, CDC should explicitly support and recognize vaccine providers that are acting in good faith with respect to administering booster doses.

   Additionally, to best get booster doses to those who need them, ACIP and CDC should explicitly support that individuals may self-attest to their primary vaccine series (e.g., primary vaccine product and date of second dose), without requiring verification or proof, which could undoubtedly lead to delays, barriers and obstacles for those who need booster protection. Moreover, it is not always feasible for vaccine providers to stock both mRNA vaccines, creating situations where a patient may need to be referred to another location to receive the properly matched mRNA vaccine. Healthcare providers worry that these situations may result in lost opportunities for immunization. Therefore, we strongly encourage the CDC and FDA to prioritize any possible review of interchangeability data.

   Furthermore, as outlined for additional doses with respect to moderately or severely immunocompromised individuals, ACIP and CDC should also recognize the need for acceptable substitutions for booster doses, for example, when it is not feasible to match the primary vaccine series product. Additionally, CDC should provide guidance for vaccine providers when the primary series information cannot be confirmed by the patient, for example, if a patient loses their vaccine card and does not recall their primary vaccine product and/or date of second dose.

   We also encourage CDC/ACIP to consider other operational considerations for boosters with unique scenarios. For example, guidance should be given on how providers should handle the possible scenario where FDA Emergency Use Authorization (EUA) is granted for the Moderna half dose. Further, NACDS strongly recommends that CDC/ACIP swiftly issue clear guidance regarding booster recommendations for patients who received non-mRNA COVID-19 vaccines, including the Janssen product and the AstraZeneca

product. These patients are eagerly awaiting more information to help ensure they are best protected from COVID-19. Pharmacies frequently receive questions from these individuals, including those fully vaccinated with the Janssen product, and those who were fully or partially vaccinated with the AstraZeneca product either outside the US or in the US as part of the AstraZeneca clinical trials, for example. These scenarios may go beyond the AstraZeneca product and may apply to other vaccines recognized by the World Health Organization (WHO). Therefore, pharmacies, and other vaccine providers, urgently need more guidance for these patients, especially regarding their eligibility for mRNA boosters.

Finally, 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 boosters and CDC's federal reporting requirements. Otherwise, CDC, ACIP, and the Department of Health and Human Services (HHS) should expressly expect all jurisdictions to abide by and maintain the federal eligibility criteria and federal reporting requirements related to boosters. Jurisdictions, states, and counties should be discouraged from developing their own eligibility criteria for purposes of COVID-19 boosters and CDC, ACIP and HHS should require the eligibility criteria determined by ACIP and CDC is followed universally across all jurisdictions, states, and counties. A unified, federal approach for future COVID-19 boosters – without variation across jurisdictions – will help create for a more seamless roll out to the American people. A national framework that is fair and consistent will help support the effective and equitable deployment and uptake of boosters across the country. As such, 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 boosters. This includes helping to ensure that reporting of boosters is simplified, and does not require the date of the patient's second dose, for example. Also, the CDC and HHS should recognize the use of "unknown" for any additional data fields as an acceptable element when such data field is indeed, unknown. 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 COVID-19 vaccinations, including boosters.

2.) To combat ongoing public hesitancy, CDC and ACIP should develop and widely publish a strong recommendation on coadministration of COVID-19 vaccines and other vaccines.

The public continues to have concerns about the coadministration of COVID-19 vaccines with other vaccines, resulting in hesitancy to receive multiple needed vaccinations during the same visit. This hesitancy continues despite approval for coadministration of COVID-19 vaccines by the ACIP in May, removal of the 14-day window, and a unanimous vote by the ACIP in June regarding coadministration of COVID-19 vaccines and flu vaccines. Therefore, NACDS recommends ACIP and CDC take additional action to instill public confidence, especially as the confluence of flu season and the roll out of COVID-19 boosters appears imminent.

A strong recommendation for coadministration of COVID-19 vaccines and other vaccines from CDC and/or ACIP would be immensely beneficial to effectively help ensure patients receive needed vaccinations without undue barriers such as multiple vaccine visits, which risks losing patients to follow up and leaving them unprotected from vaccine-preventable illness. More than a third of Americans receive their flu vaccination at pharmacies each year, providing accessibility and convenience to receive a COVID-19 vaccine at the same time when indicated and eligible. A strong and widely published recommendation on

coadministration is critical (e.g., MMWR) to help alleviate patient concerns and hesitancies. Further, CDC should include coadministration as a key message in its public messaging campaign to help instill vaccine confidence among people in America.

3.) The Centers for Medicare and Medicaid Services (CMS) should quickly address ongoing COVID-19 vaccination reimbursement challenges and provide additional guidance to payers in light of a forthcoming recommendation on COVID-19 boosters for the general population.

NACDS appreciates CMS' swift efforts to update the CMS COVID-19 Vaccine Provider Toolkit with guidance on additional doses for immunocompromised individuals. However, specific guidance and updates are not yet available regarding booster doses for the general population. Therefore, we urge CMS to make the necessary updates and provide guidance to all payers regarding booster doses for the general population as soon as possible via its COVID-19 Provider Toolkit.[1]

Further, to help promote access, CMS should support patient attestation in its programs regarding primary vaccine series (product and date of second dose) for additional doses and boosters. We urge CMS to clarify that it will align with the ACIP guidance for all components of dose 3 vaccine administrations and booster doses to minimize confusion and establish consistency across provider types for vaccine administration. Additionally, given that ACIP recommended matching product for the third dose to the primary series for immunocompromised individuals when feasible, allowing for substitutions if needed, it is likely that the same scenario may also occur for booster doses. Therefore, we encourage CMS to adjust their systems to support scenarios where the additional dose or booster product does not match the primary vaccine series, given that ACIP has allowed for substitutions when matching is not feasible. We also encourage CMS to expect this proactive adjustment for other payers well before the announcement of the booster vaccine guidance.

Additionally, we encourage CMS to update their systems (rejects and edits) to accommodate both the 28-day minimum interval for additional doses for immunocompromised individuals and the potential 8-month minimum interval for booster doses for the general population. As stated above, we also encourage CMS to expect this proactive adjustment for other payers well before the announcement of the booster vaccine guidance. CMS should implement and encourage other payers not to implement their own arbitrary, minimum interval requirements for administration of the third dose or booster dose such as 180 days. Inappropriate execution of the recommended minimal intervals may cause serious barriers, delays, and high vaccine provider burden to work through rejections and resubmissions, which should be avoided to support seamless booster access for the nation.

Also, NACDS greatly appreciates CMS' updated COVID-19 vaccine rates for at-home vaccinations and within smaller group homes, assisted living facilities, and other group living situations to help advance access to these high-risk individuals. We urge CMS to continue to evaluate whether payment for the administration of the vaccine under federal programs and for commercial payers is reasonable and adequate reimbursement to cover vaccine providers' costs in all settings.

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[1] Specifically, CMS should reference in its Provider Toolkit the existing standardized systems updates from NCPDP. System rules should be updated in alignment with the standardized provisions found in the NCPDP Emergency Preparedness Guidance document, section 10.5.

Separately, millions of Americans who received the Janssen COVID-19 vaccine await more information regarding additional doses or boosters. However, some of these individuals do not want to risk the wait and are seeking additional protection by requesting mRNA vaccines without disclosing their previous vaccination. Given these challenging situations, NACDS urges CMS to encourage federal programs and other payers not to penalize vaccine providers acting in good faith should patients seek additional vaccination protection and consider offering guidance on how providers may be able to seek payment for the administration of such vaccine under this scenario.

4.) **HHS and CDC should proactively address challenges on the horizon for 2022 to help ensure an unrelenting, vigorous pandemic response effort.**

Especially with the anticipated rollout of booster doses for the general population starting in late September, NACDS continues to emphasize the importance of amending the current PREP Act declaration to include an extension beyond the declared Public Health Emergency (PHE). Public health officials have indicated that COVID-19 booster doses will be needed for individuals into 2022 and likely beyond. Therefore, the authorities granted under the PREP Act declaration that have allowed pharmacies to advance national access to vaccines and testing should be extended beyond the PHE to help ensure uninterrupted public access for the totality of the nation's response and recovery.

We strongly urge HHS to take swift action to amend the current PREP Act declaration to include an extension for authorities granted to pharmacy personnel beyond the declared PHE until at least October 2024 in order for pharmacists to order and administer, and pharmacy technicians and interns to administer, COVID-19 vaccines, COVID-19 tests, and all ACIP-recommended vaccines to individuals 3 years and older; in addition to technicians and interns administering flu shots to adults. This is in alignment with the expiration date set for other "qualified persons" identified under the declaration.[2] Additionally, we encourage CMS and other payers to proactively address problems that could hinder reimbursement for these critical services, should the PHE expire, to help ensure the public does not lose essential, convenient access to COVID-19 vaccines and testing at their local, trusted pharmacies.

Similarly, we also recommend the Biden Administration ensure sufficient vaccine product, including boosters, for the U.S. for at least 12 continuous months after the public health emergency or until the pandemic ends, or in other words, when the virus becomes endemic, or otherwise, when herd immunity is reached.

In closing, pharmacies greatly appreciate the Biden Administration's planning efforts to help ensure systems and operations are prepped and equipped in advance of COVID-19 boosters being operationalized. Such planning helps support a more seamless rollout to the public, tentatively planned for the week of September 20th. NACDS looks forward to the continuation of proactive, coordinated, and straightforward messaging across all federal entities and the media regarding when and how members of the general public can expect to receive boosters, tailored by regulatory actions, operational realities, and other planning. We would also encourage Federal agencies to ramp up

[2] *See* HHS, Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19, *available at* https://www.phe.gov/Preparedness/legal/prepact/Pages/PREP-Act-Guidance.aspx.

communications efforts in synergy with vaccine providers, including pharmacies, to drive vaccination uptake, both for COVID-19 vaccines and other co-administered vaccines, including flu shots.

We would like to discuss these recommendations at your earliest convenience. For any questions or further discussion, please contact NACDS' Sara Roszak, Senior Vice President, Health and Wellness Strategy and Policy, at sroszak@nacds.org or 703-837-4251.

Sincerely,

Steven C. Anderson, FASAE, IOM, CAE
President and Chief Executive Officer