Dr. Johnathan Mermin, Director of NCHHSTP
Dr. Neblett Fanfair, Director of the Division of HIV Prevention

Noah Aleshire, Chief Regulatory Officer
% Jeffrey M. Zirger, Information Collection Review Office

Centers for Disease Control and Prevention (CDC)
1600 Clifton Rd NE, MS H21-8
Atlanta, Georgia 30329

Submitted electronically via http://www.regulations.gov

Re: Public Comments Requested on draft "Recommendations for HIV Screening in Clinical Settings," Docket CDC-2024-0100

Dear Dr. Mermin, Dr. Fanfair, and Mr. Aleshire:

The Center for HIV Law and Policy (CHLP) submits the following comments on the CDC's draft "Recommendations for HIV Screenings in Clinical Settings," published in the Federal Register on December 2, 2024, as a proposed update to the 2006 "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings.'' We submit these comments on behalf of the listed organizations, which represent a cross-section of groups that specialize in HIV-related legal policy advocacy, LGBTQ+ legal policy and litigation, individual and civil rights policy and litigation, disability justice, reproductive justice, direct services for those who are discriminated against or disenfranchised due to HIV stigma, or membership-based organizations for people living with HIV. In submitting these comments, CHLP is joined by: AVAC, The American Civil Liberties Union (ACLU), Disability Rights Education and Defense Fund (DREDF), Health HIV, Lambda Legal, Legal Action Center (LAC),

Positive Women's Network USA (PWN), Transgender Law Center (TLC), US People Living With HIV Caucus, and The Well Project.

These organizations have come together to provide expert feedback on the proposed updates due to our desire to improve the lives of those living with and deeply affected by HIV as well as expand equitable access to HIV testing. We are deeply concerned that the proposed recommendations, while trying to achieve laudable goals, do so in such a way that represents an unnecessary loss of patients' rights and bodily autonomy. In fact, the proposed recommendations run the risk of being counterproductive due to causing needless exacerbation of deep-seated medical mistrust within many of the communities hardest hit by the HIV epidemic through decreasing their ability to engage in shared decision-making with their medical providers and give direct and unequivocal informed consent for every part of their care. We believe that the goals of expanding equitable access to testing and improving public health through the linkage of people to care can be achieved with simple, evidence-based modifications to the proposed plan. We challenge everyone reading this to ask themselves, "If the problem is a lack of testing, why does the offered solution have to undermine patients' informed decision-making?"

I. The Recommendations by the CDC: (1) use much of its evidence out of context; (2) make assumptions unsupported by the evidence; and (3) minimize or fail to address certain harms.

A. The proposed update increases the accessibility of HIV testing, however does so by replacing a person's ability to give informed consent with, at best, indirect notice.[1]

There are several sections to the proposed updates to the 2006 "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings."[2] One section modifies the upper and lower age limits for which testing is recommended. The revision removing the upper age limit for which HIV testing is recommended comes after years of advocacy by many organizations concerned with the needs and rights of aging people and is a very welcome change.

In relevant part, a large section addresses the implementation of HIV screening, defined as "routine HIV test administration to persons in clinical settings absent provider knowledge of the patient's potential HIV risk exposure."[3] This is the kind of "routinization" of HIV testing, absent exploration of a person's individual medical, sexual, and social history to assess for indications

[1] Author would like to note that the use of "informed consent" does not mean that we are advocating for an "opt-in" regime of testing. Informed consent, where a person is able to make an informed decision on whether or not to engage in a form of medical care, is a part of "opt-out" testing as well. It is, in fact, implied in the phrase "opt-out" testing as distinct from mandatory testing, where one's desire to consent, informed or otherwise, is not taken into account.

[2] Draft "Recommendations for HIV Screenings in Clinical Settings," 89 Fed. Reg. 95793. https://www.regulations.gov/document/CDC-2024-0100-0002.

[3] "Draft Recommendations" at 1, lines 10-11.

of increased vulnerability to HIV, or "risk factors," that the CDC has been promoting and has been the subject of many studies, some of which form the basis of the CDC's recommendation. The goal is to increase the total number of people who know their status while decreasing the biased targeting by providers of members of certain populations for HIV testing (in a manner that increases medical mistrust) that leads to neglecting to test others, such as aging people.

The CDC further states that Clinical Decision Support Systems (CDSS) should be used to automate HIV tests on blood, even if collected for other purposes if the person's electronic medical health record (EMR) does not show evidence of one previous HIV test if the medical facility is located in a geographic area where the incidence of HIV in the population is greater than .5% prevalence.[4] In facilitation of this automation, the CDC supports a combination of a "general consent process as used for other routine tests" and standing HIV laboratory test orders for HIV screening in healthcare settings.[5] It is important to note that no definition for "general consent process" is provided, leaving unclear if the recommendation is just for an HIV test to be covered under a standard general consent to "test and treat" and never explicitly mentioned, as a separate "line item" buried in the general consent form, or some other "general consent process" that meets the minimal requirements under state law. It is further important to note that whether made routine or otherwise, currently the results of an HIV test have significantly more of an impact on a person's life, in large part due to HIV stigma, than other "routine" test results. Regardless of the exact mechanism, the CDC recommendations implicitly direct providers to automate everything in such a way that there is no requirement for direct engagement before an HIV test is provided to people seeking medical care for any reason if a blood test is ordered. This protocol is, however, considered under the recommendations to remain a form of "opt-out" testing, where the person has the ability to ask questions of the provider and refuse testing if they wish. It therefore remains incumbent upon the person to explicitly decline testing if they wish, though it is unclear exactly by what mechanism they would be aware that a test was being ordered in the first place.

Of particular concern is the recommendation that if a preliminary test is performed and comes back positive, providers should only inform the person of those results before they leave the medical facility, with the caveat that additional testing is necessary to confirm the diagnosis, if the provider believes they will lose contact with the person.[6] The ostensible purpose of this seems to be so people are not unduly concerned by a false positive. However, this would mean in practice that many people will get life-altering test results based on a test that they had no real knowledge was being performed, days after leaving the medical facility, potentially through

[4] "Clinical decision support systems (CDSS) are comprised of various tools to enhance decision-making about patient care including computerized alerts and reminders to healthcare providers and patients condition-specific order sets, focused patient data reports and summaries, documentation templates, and diagnostic support." *Community Preventative Services Task Force Finding and Rationale Statement* (Community Preventative Services Task Force, 2020), 2, https://www.thecommunityguide.org/media/pdf/HIV-CDSS-508.pdf.
[5] "Draft Recommendations" at 1, lines 8-9.
[6] "Draft Recommendations" at 6, lines 209-212.

electronic notification by their EMR portal prior to ever speaking to a medical professional about it. There are no guidelines provided in regards to who will contact the person and what kind of training that contactor should have. And as will be dealt with in more detail below, one's experience with caretakers at any point of the HIV care continuum can directly impact their willingness to enter and/or remain in care.

B. The recommendations proposed by the CDC are not fully supported by the evidence provided, nor do they use all of the evidence provided in its correct context.

Although the Recommendations contain a breakdown of the methodology that was used to select the sources relied upon, and references to findings in those sources, the Recommendations when viewed as a whole are not supported by the evidence. There appears to be no one study that examines the impact on numbers of people tested, and importantly, their linkage to and retention in care, under a routinization scheme that combines the following factors: (1) buried notice of an HIV test in the general consent form; (2) no point at which the person being tested is given any form of direct notice, such as oral notice; (3) reliance upon standing orders for non-targeted testing; (4) allows for the person being tested to leave the medical facility without being informed they were tested; (5) fails to include a robust scheme for training professionals and/or directing how follow up should be achieved. While the studies cited examine the impact of different portions of the screening scheme proposed, due to the harmful impact of the Recommendations in totality on people's ability to meaningfully participate in their care, one would expect the proposed plan to be supported in its cohesive entirety by extensive and overwhelming evidence of its benefits.

In terms of the use of CDSS tools, primarily in the form of EMR alerts, there is a significant amount of evidence provided that the alerts do increase the raw numbers of people tested for HIV, with varying impact on the number of new diagnoses and eventual linkage to care. Across the studies, the point at which alerts are given; whether they are passive or active stops in the use of the EMR system; what type of provider (nurse, doctor, trained counselor, etc.) they are given to; and exactly what that provider is supposed to do after receiving an alert varies, but regardless of the protocol the impact on raw numbers of people tested is significant and beneficial. However, none of the cited studies go as far into "automation," and its commiserate removal of direct notice and ability to give informed consent, as the CDC now proposes.

Two studies cited in "Appendix C" in support of the use of CDSS tools are ones completed by Burrell et al. in 2021 and White et al. in 2018.[7] Both of these studies document, as indicated in

[7] "Guidelines for HIV Screening: Appendices," 89 Fed. Reg. 95793. https://www.regulations.gov/document/CDC-2024-0100-0003. Citing Carmen N. Burrell et al., "Using the Electronic Medical Record to Increase Testing for HIV and Hepatitis C Virus in an Appalachian Emergency Department," *BMC Health Services Research* 21 (2021): 524, https://doi.org/10.1186/s12913-021-06482-5; Douglas A.E. White, MD et al., "A Comparative Effectiveness Study of Two Nontargeted HIV and Hepatitis C Virus

"Appendix C," that a CDSS tool increased testing with statistical significance. The White test is highlighted as showing that automated laboratory orders were vast improvements over nurse-initiated testing (particularly in a scheme where the HIV testing was recommended, offering it was nonmandated, and a person's exclusion was entirely at the discretion of the nurse).[8] But in the White study, unlike in the plan recommended by the CDC, when the testing was automated the ER had voluminous signage on the walls and in every triage cubicle announcing the fact that HIV testing would be performed on one's blood if drawn for any purpose without a person explicitly opting out. Most importantly, Triage nurses were *required* to read a template letting patients know about the HIV testing policy.[9] Therefore, participants in the White study were given written and verbal notice of the HIV testing policy and a meaningful opportunity to ask their questions and/or opt -out of testing. Similarly, in the Burrell study, the EMR was configured to trigger a Best Practice Alert (BPA) which the provider or nurse could click away after informing the person about the policy regarding HIV tests on blood collected and asking whether they wanted to opt -out of testing.[10] Notably, this study also included a robust program of trained Patient Navigators tasked with meeting with or following up with people who screened positive in order to assist in their linkage to care. These studies do support, as the CDC asserts, that the use of CDSS tools increases the number of people tested. However, they do not stand for the proposition that testing numbers will be improved, and importantly, that subsequent linkage to care by those tested will be improved, through the recommendations conveyed in the CDC's draft. Though studies have shown that people when given the opportunity to opt out do so, the majority of people do not, and the ability to opt out is important in a medical system that claims to value the informed consent of those who use it.

Furthermore, even if including notice of HIV testing and one's ability to opt out in the general consent meets the letter of the law, it is inconsistent with medical ethics regarding informed consent and counter to the medical community's movement towards true shared decision-making between person and provider.[11] The proposal to replace a conversation with your medical

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Screening Algorithms in an Urban Emergency Department," *Annals of Emergency Medicine* 72, no. 4, (2018): 438-448, https://doi.org/10.1016/j.annemergmed.2018.05.005.

[8] White, "Comparative Effectiveness," at 440. The findings in this study mirror those in another study cited by the draft recommendations themselves. "Draft Recommendations" at footnote 58. In that study, done in 2019 by Sha, there was a marked drop off in testing rates when the BPA moved to a "passive" place in the workspace so providers did not have to offer testing to be able to move on in the EMR. When testing was moved to an automatic algorithm where it was ordered if blood was being drawn, the nurse drawing the blood was required to inform the patient that their blood would be tested for HIV unless they declined. See Beverly E. Sha, MD et al., "Evolution of an Electronic Health Record Based–Human Immunodeficiency Virus (HIV) Screening Program in an Urban Emergency Department for Diagnosing Acute and Chronic HIV Infection," *The Journal of Emergency Medicine* 57, no. 5, (2019): 733-734, https://doi.org/10.1016/j.jemermed.2019.08.008.

[9] White, "Comparative Effectiveness," at 440.

[10] Burrell, "Appalachian Emergency," at 3.

[11] J Rodrigues et al., "Clinical Guidelines Program Approach to Shared Decision-Making." (Clinical Guidelines Program, 2023), https://www.hivguidelines.org/guideline/hiv-testing-resources/?mytab=tab_0&mycollection=hiv-testing-acute-infection.

provider with any other form of indirect notice—merely a poster in the waiting room or buried within the general consent forms—is tantamount to no notice at all. Does a person in a busy emergency room or chasing a mischievous toddler have the real ability to read information posted on the wall? How many people actually read the fine print? What if a person has difficulty reading the language and feels uncomfortable disclosing this difficulty? Or if they are visually disabled and are not given ADA-mandated supports? The proposed changes do not consider the fact that many people have different reading comprehension abilities and would be unable to read written materials, such as the general consent form. Prioritizing automatically testing people for HIV over their bodily autonomy and ability to know about and understand every step of their medical care is not only contrary to medical ethics it is also, frankly, not necessary to achieve the goal of increased testing. It is therefore unclear based upon the provided support by the CDC the need for entirely removing direct notice, even in the form of a two or three-sentence script, from the process of opt-out routine HIV testing. Removing direct notice is a giant step, for which there should be a similarly large amount of data to support before even considering, let alone implementing.

C. The Proposed Plan Minimizes or Fails to Address Harms it Will Inevitably Cause

The CDC's recommendations do not only fail to address not only the barriers and stigma that drive people to not know their HIV status, they also fail to contemplate the real harm that the automated testing scheme will cause. The sole harms focused on by the CDC are the number of false positives that may arise through initial screening as well as the cost effectiveness of the proposed plan.[12] The concern about false positives from the first screening test, and not wanting to cause people unnecessary concern, runs counter to the plan in its entirety—a plan where people's first indication that they received an HIV test is when they check their EMR portal after arriving home and see the results. How could finding out you were tested without your consent, let alone your HIV status, not cause "unnecessary" concern? The real harm that this scheme will cause is the further erosion of trust between those who have been hardest hit by the HIV epidemic and the medical system.

The groups that have been hardest hit by the HIV epidemic nationally, especially Black and Latine people, especially those who live in the South, are also people who have a fraught history with the medical system; a breach in patient self-determination, such as administering an HIV test without their informed consent, may drive them out of care. Nationally, many Black and Latine people have a deep-seated distrust of the medical establishment, especially when it relates to HIV prevention, testing, and care.[13] Although they may trust their individual medical

[12] "Draft Recommendations" at 3-4.

[13] C.O. Cunningham. MD et al., "HIV Status, Trust in Health Care Providers, and Distrust in the Health Care System Among Bronx Women," *AIDS Care* 19, no. 2 (2007): 226–234, https://doi.org/10.1080/09540120600774263; See also Somnath Saha, et al., "Trust in Physicians and Racial

providers (if they have them), they may differentiate those from the larger, faceless medical system.[14] If they are subject to a routine HIV screening test being administered by a hospital and/or large medical institution without their informed consent and while they are there for an unrelated reason, one can almost guarantee that will increase their mistrust of the medical system. Core principles such as "informed consent" and "shared decision-making" exist in part to improve provider/patient communication and relations, and to help build a foundation of trust. Further erosion of trust may make people more resistant to entering into and remaining in care for their HIV, if not driving them away from seeking medical care altogether.[15] Being told one's status, even after knowingly consenting to testing, can be understandably traumatizing; being told the same information without understanding one was being tested is even more so.[16]

Although we agree that testing must be made more accessible and rates of testing must climb, by itself, testing people without their informed consent only notifies people of their status. It will not address the reasons that they may have actively avoided learning their status previously. It will not necessarily cause people to become engaged in HIV care, or overcome systemic barriers that may have made them vulnerable to HIV in the first place. Finally, due to the de-emphasis by the CDC recommendation on provider education and frank conversation with folks who are tested, it will not necessarily result in the changes of behavior that the CDC seeks to encourage through people learning their status.[17] It will, however, result in widening the rift between marginalized groups and the medical system, a rift that was caused by the medical system and whose responsibility it is to bridge.

II. Simple Evidence-Based Changes would Address the Issues Identified in Part I While Still Achieving the Goal of Increased Testing

As stated previously, increasing the number of people who have access to testing and know their status so they can receive care is a laudable goal. The issue with the proposed changes is not the end, it is the means. However, there are simple evidence-based changes that can be made to the proposed plan for routine testing that would address these concerns while still achieving the CDC's goals.

Disparities in HIV Care," *AIDS Patient Care and STDs* 24, vol. 7, (July 17, 2010): 415–420, https://doi.org/10.1089/apc.2009.0288 (examining the impact that trust in providers had on adherence to ART in Black people in Baltimore).

[14] Cunningham, "HIV status, Trust."

[15] Alison Wringe et al., "HIV Testing Experiences and Their Implications for Patient Engagement with HIV Care and Treatment on the Eve of 'Test and Treat': Findings From a Multicountry Qualitative Study," *Sexually Transmitted Infections* 93, Suppl. 3, (2017), https://doi.org/10.1136/sextrans-2016-052969.

[16] Carol L. Galletly J.D., Ph.D. et al., "CDC Recommendations for Opt-Out Testing and Reactions to Unanticipated HIV Diagnoses," *AIDS Patient Care STDS* 22, vol. 3, (March 2008): 189-193, http://10.1089/apc.2007.0104.

[17] Many studies as well as the NIH's own website about testing cite the statistic that 40% of new HIV cases can be traced back to a person who did not know their HIV status. *HIV Testing: Key Points* (NIH, 2024), https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-testing.

For example, evidence shows that the use of CDSS prompts increases the number of people tested, and they are therefore an essential component of any plan that looks to expand testing. It is noted, however, if the offering of tests is not mandated that the number of tests completed drops. An easy solution to this problem, used in studies such as the 2019 one by Sha, is by making those prompts "active" instead of "passive," so that it must be addressed prior to the medical provider being able to move on with the visit.[18] This could be, and has been, done by anyone from the physician, to the check-in person who gathers a person's insurance information and has them sign consents in the first place.[19] Standing orders can potentially still be utilized, dependent on state law, to limit the concerns raised about "Alert Fatigue" for providers.[20] And, consistent with what occurred in the studies discussed above, this prompt can require oral notification of testing so that a person has an actual opportunity to opt out or to request an opportunity to ask questions so they can give informed consent.

A change in the kind of EMR prompt given in the example above ensures that a person will at minimum have oral notice of the hospital's testing policy and that they have the opportunity to ask questions before deciding to opt out. This combined with other simple efforts can make sure that routine HIV testing policies enshrine informed consent and shared decision-making as part of the process. It is the CDC's duty to promote public health; and central to the ability to achieve that duty is to create an environment where people believe they have bodily autonomy and a real say in their medical care. Most people do not go to the doctor because they want to, they go because they have to. Any changes to the HIV testing policy should be certain to encourage people to still be going.

III. Conclusion

The above includes simple but critical recommendations for changes that the CDC can easily make to their proposal that will not only accomplish the goal we share of expanding equitable access to HIV testing but also protect the important rights of people to give informed consent to any and all medical testing that occurs during their medical care. It is by protecting that right that the CDC can truly encourage people to not only know their status but also to engage in the necessary care afterward. At minimum:

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[18] Sha, "Evolution of An Electronic Health Record."

[19] Patient education was further supported through the provision of a handout with HIV testing information. If the patient declined when asked by the intake staff member, the triage nurse would ask a second time which caused most patients to no longer opt out. Natasha S. Crumby et al., "Experiences Implementing a Routine HIV Screening Program in Two Federally Qualified Health Centers in the Southern United States," *Public Health Reports* 131. Suppl. 1, (2016): 21-9, https://pmc.ncbi.nlm.nih.gov/articles/PMC4720603/.

[20] Known variously as "alert fatigue," "BPA fatigue," and "provider fatigue," several articles discuss different ways to address the drop off in administered tests caused by providers declining to offer HIV tests if they were able to do so due to a feeling of being overworked, or that it was an unnecessary use of their time. See e.g. Sha, "Evolution of An Electronic Health Record," at 736. The study authors contemplated or applied different solutions to combat "alert fatigue," including only having the alert come up when a blood test had already been ordered for another reason. See Sha, "Evolution of An Electronic Health Record."

- The CDC must ensure that all people tested for HIV are given direct notice of a facility's HIV testing policy;
- This notice must include a reference both to the ability to ask questions and to opt out of testing; and
- This notice must be provided in a clear manner, not simply buried in a general consent form, so that it is unequivocal that it was received. This may include changing the form of notice given to account for each individual's needs due to disability or language barrier.

Thank you for the opportunity to provide input on this important update. If there are any follow-up questions, please contact Kae Greenberg, CHLP Staff Attorney, kgreenberg@hivlawandpolicy.org, and Amir Sadeghi, CHLP Policy and Advocacy Manager, amir@hivlawandpolicy.org.

Sincerely,

CHLP

AVAC

The American Civil Liberties Union (ACLU)

Disability Rights Education and Defense Fund (DREDF)

HealthHIV

Lambda Legal

Legal Action Center (LAC)

Positive Women's Network-USA

Transgender Law Center (TLC)

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