Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation

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HHS's proposed Framework to Support and Accelerate Smoking Cessation is an important first step to addressing health disparities among populations disproportionately impacted by smoking-related illness and death. In particular, the framework focuses on closing the gap in culturally tailored cessation treatments and programs available, improving accessibility to these disproportionately impacted populations, and acknowledging the importance of policies and programs at the population level that will support an individual's successful attempts to quit smoking. While we generally support the proposed framework's goals, cross-cutting principles, and broad strategies, we offer some suggestions to strengthen the framework and increase impact on preventing cancer deaths and other smoking-caused deaths.

1. Are the proposed goals appropriate and relevant for addressing the needs of populations disparately affected by smoking?

The proposed goals are relevant and do address disparately affected populations. However, ***the framework would have greater impact if tobacco cessation goals were integrated with tobacco policy and comprehensive tobacco control programs.*** We need a coordinated, multidirectional and aligned effort that supports both policies that promote and facilitate successful smoking cessation and smoking cessation programs that are integrated with policy implementation. A comprehensive approach to cessation recognizes not only that individuals should be encouraged to quit smoking using evidence-based strategies, but policies and

programs that create new normalized environments where quitting smoking is easier, affordable, and acceptable are also essential.[1,2,3]

Comprehensive and integrated tobacco control policies aimed at social equity,[4] such as eliminating the sales and manufacturing of menthol [5] and other flavored tobacco products, provide powerful cessation opportunities for people who disproportionately use these products.[6] These policies are particularly relevant to populations living below the federal poverty line,[7,8] those who identify as racial/ethnic or sexual gender minorities, [9] and those with mental health and/or substance use disorders [10] where tobacco use is concentrated and contributes substantially to increased morbidity and mortality. A coordinated and integrated approach that includes cessation-focused tobacco control policies with access to evidence-based cessation services could substantially reduce the tobacco related burden in these populations.

The disproportionate toll of tobacco-related burden on some subpopulation groups is a social injustice. Tobacco documents disclosing the social justice implications of predatorily promoted

[1] Hafez AY, Gonzalez M, Kulik MC, Vijayaraghavan M, Glantz SA. Uneven Access to Smoke-Free Laws and Policies and Its Effect on Health Equity in the United States: 2000-2019. Am J Public Health. 2019 Nov;109(11):1568-1575. doi: 10.2105/AJPH.2019.305289. Epub 2019 Sep 19. PMID: 31536405; PMCID: PMC6775904.

[2] Vijayaraghavan M, Hartman-Filson M, Vyas P, Katyal T, Nguyen T, Handley MA. Multi-Level Influences of Smoke-Free Policies in Subsidized Housing: Applying the COM-B Model and Neighborhood Assessments to Inform Smoke-Free Policies. Health Promot Pract. 2023 May 20:15248399231174925. doi: 10.1177/15248399231174925. Epub ahead of print. PMID: 37209138.

[3] McCuistian C, Kapiteni K, Le T, Safier J, Delucchi K, Guydish J. Reducing tobacco use in substance use treatment: An intervention to promote tobacco-free grounds. J Subst Abuse Treat. 2022 Apr;135:108640. doi: 10.1016/j.jsat.2021.108640. Epub 2021 Oct 23. PMID: 34743925; PMCID: PMC8903046.

[4] Mills SD, Rosario C, Yerger VB, Kalb MD, Ribisl KM. Recommendations to advance equity in tobacco control. Tob Control. 2022 Dec 19:tc-2022-057670. doi: 10.1136/tc-2022-057670. Epub ahead of print. PMID: 36535756; PMCID: PMC10277310.

[5] Yerger V. What more evidence is needed? Remove menthol cigarettes from the marketplace-now. Tob Control. 2022 Jul;31(4):493-494. doi: 10.1136/tobaccocontrol-2021-056988. Epub 2021 Sep 16. PMID: 34535506.

[6] Froelicher ES, Doolan D, Yerger VB, McGruder CO, Malone RE. Combining community participatory research with a randomized clinical trial: the Protecting the Hood Against Tobacco (PHAT) smoking cessation study. Heart Lung. 2010 Jan-Feb;39(1):50-63. doi: 10.1016/j.hrtlng.2009.06.004. Epub 2009 Jul 22. PMID: 20109986.

[7] Vijayaraghavan M, King BA. Advancing Housing and Health: Promoting Smoking Cessation in Permanent Supportive Housing. Public Health Rep. 2020 Jul/Aug;135(4):415-419. doi: 10.1177/0033354920922374. Epub 2020 Apr 30. PMID: 32353245; PMCID: PMC7383751.

[8] Brown T, Platt S, Amos A. Equity impact of population-level interventions and policies to reduce smoking in adults: a systematic review. Drug Alcohol Depend. 2014 May 1;138:7-16. doi: 10.1016/j.drugalcdep.2014.03.001. Epub 2014 Mar 13. PMID: 24674707.

[9] Lee JGL, DeMarco ME, Beymer MR, Shover CL, Bolan RK. Tobacco-Free Policies and Tobacco Cessation Systems at Health Centers Serving Lesbian, Gay, Bisexual, and Transgender Clients. LGBT Health. 2018 May/Jun;5(4):264-269. doi: 10.1089/lgbt.2017.0208. Epub 2018 Apr 16. PMID: 29658846; PMCID: PMC6913102.

[10] Guydish J, Wahleithner J, Williams D, Yip D. Tobacco-free grounds implementation in California residential substance use disorder (SUD) treatment programs. J Addict Dis. 2020 Jan-Mar;38(1):55-63. doi: 10.1080/10550887.2020.1713687. Epub 2020 Jan 25. PMID: 32186480.

tobacco products could help those subpopulation groups quit smoking.[11] For example, African American smokers might be mobilized toward quitting after reviewing tobacco industry documents about racial targeting by the industry. It has also been shown that the use of tobacco documents revealing the tobacco industry's attempt to co-opt major black leadership organizations and its pervasive marketing of menthol cigarettes in low-income African American communities may be an essential component of a culturally tailored cessation program.[12] Additionally, some individuals smoke to alleviate stress associated with experiences living with social, economic, and environmental inequities. Cessation interventions should recognize the need to target stress as an underlying cause of smoking.[13]

A comprehensive HHS approach to supporting tobacco cessation should include coordination with and strong support for the FDA to remove menthol and its analogs as an additive from all commercial tobacco products (FDA's proposed rule would remove menthol as a characterizing flavor from cigarettes and cigars, but not from e-cigarettes), while also reducing nicotine to non-addictive levels.[14] Just reducing the level of nicotine in tobacco products without also simultaneously removing menthol will not support cessation, as the presence of menthol in low nicotine products will still elicit a "liking response" and encourage the continued use of these products. Because retailer density impacts tobacco cessation,[15,16,17] HHS should support state and local efforts to restrict or end tobacco sales[18,19] and implement comprehensive clean indoor air laws. Federal media campaigns should be expanded and continuously funded at levels with high population exposure, as these campaigns increase cessation behavior, including to

[11] Froelicher ES, Doolan D, Yerger VB, McGruder CO, Malone RE. Combining community participatory research with a randomized clinical trial: the Protecting the Hood Against Tobacco (PHAT) smoking cessation study. Heart Lung. 2010 Jan-Feb;39(1):50-63. doi: 10.1016/j.hrtlng.2009.06.004. Epub 2009 Jul 22. PMID: 20109986.

[12] Yerger VB, Daniel MR, Malone RE. Taking it to the streets: Responses of African American young adults to internal tobacco industry documents. Nicotine Tob Res 2005;7:163-72

[13] Mills SD, Rosario C, Yerger VB, Kalb MD, Ribisl KM (2022). Advancing equity in tobacco control. Journal Tobacco Control, 0:1–8. doi:10.1136/tc-2022-057670

[14] Benowitz NL, Warner KE, Myers ML, Hatsukami D, Berman ML, Vallone D, Cohen JE. How the FDA Can Improve Public Health - Helping People Stop Smoking. N Engl J Med. 2023 Apr 27;388(17):1540-1542. doi: 10.1056/NEJMp2301700. Epub 2023 Apr 22. PMID: 37092791.

[15] Valiente R, Escobar F, Urtasun M, Franco M, Shortt NK, Sureda X. Tobacco Retail Environment and Smoking: A Systematic Review of Geographic Exposure Measures and Implications for Future Studies. *Nicotine Tob Res.* 2021;23(8):1263-1273.

[16] Halonen JI , Kivimäki M , Kouvonen A , et al . Proximity to a tobacco store and smoking cessation: a cohort study. Tob Control 2014;23:146–51. doi:10.1136/tobaccocontrol-2012-050726.

[17] Hoek J, Gifford H, Pirikahu G, Thomson G, Edwards R. How do tobacco retail displays affect cessation attempts? Findings from a qualitative study. *Tob Control.* 2010;19(4):334-337.

[18] Chapman S, Freeman B. Regulating the tobacco retail environment: beyond reducing sales to minors. Tob Control. 2009;18(6):496-501.

[19] Chaiton M, Dubray J, Guindon GE, Schwartz R. Tobacco Endgame Simulation Modelling: Assessing the Impact of Policy Changes on Smoking Prevalence in 2035. *Forecasting*. 2021; 3(2):267-275. https://doi.org/10.3390/forecast3020017

disparately affected focus population groups[20,21,22,23] whey they are sustained.[24] Media campaigns should include communications tailored for priority populations, as such media campaigns have been shown to increase cessation in the general population.[25,26]

Additionally, we recognize that HHS's Request for Information states that it is focused on cessation of the use of commercial cigarettes, cigars, and cigarillos, and not on use prevention and cessation of other nicotine products such as e-cigarettes. However, ***cessation program strategies that only address combustible products will not be as effective as developing a coordinated strategy that addresses quitting other forms of tobacco and nicotine products***. This is because it takes many attempts to quit smoking,[27] and without cessation support, former smokers are likely to migrate to other nicotine products and/or become dual users[28] rather than achieve complete cessation. In addition, some tobacco control policies with potential for major impacts on prevalence and disparities may benefit from careful consideration of the interplay between combustible and non-combustible regulation. For example, removing menthol and taking nicotine to non-addictive levels may have differential effects and require different supports depending upon whether it is removed from all tobacco products or solely from combustible products.

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[20] Davis KC, Patel D, Shafer P, et al. Association Between Media Doses of the Tips From Former Smokers Campaign and Cessation Behaviors and Intentions to Quit Among Cigarette Smokers, 2012-2015. Health Education & Behavior. 2018;45(1):52-60. doi:10.1177/1090198117709316.

[21] McAfee T, Davis KC, Shafer P*, et al*. Increasing the dose of television advertising in a national antismoking media campaign: results from a randomised field trial. *Tobacco Control* 2017;**26:**19-2.

[22] Judith J Prochaska, PhD, MPH and others, The 2016 *Tips From Former Smokers®* Campaign: Associations With Quit Intentions and Quit Attempts Among Smokers With and Without Mental Health Conditions, *Nicotine & Tobacco Research*, Volume 21, Issue 5, May 2019, Pages 576–583,

[23] England L, Tong VT, Rockhill K, Hsia J, McAfee T, Patel D, Rupp K, Conrey EJ, Valdivieso C, Davis KC. Evaluation of a federally funded mass media campaign and smoking cessation in pregnant women: a population-based study in three states. BMJ Open. 2017 Dec 19;7(12):e016826. doi: 10.1136/bmjopen-2017-016826. PMID: 29259054; PMCID: PMC5778314.

[24] Wakefield MA, Loken B, Hornik RC. Use of mass media campaigns to change health behaviour. Lancet 2010;376(9748):1261–71. Durkin S, Brennan E, Wakefield M. Mass media campaigns to promote smoking cessation among adults: an integrative review. *Tobacco Control* 2012;**21:**127-138.

[25] Durkin SJ, Brennan E, Wakefield MA. Optimising tobacco control campaigns within a changing media landscape and among priority populations. Tob Control. 2022 Mar;31(2):284-290. doi: 10.1136/tobaccocontrol-2021-056558. PMID: 35241601.

[26] Davis KC, Patel D, Shafer P, et al. Association Between Media Doses of the Tips From Former Smokers Campaign and Cessation Behaviors and Intentions to Quit Among Cigarette Smokers, 2012-2015. *Health Education & Behavior*. 2018;45(1):52-60.

[27] Chaiton M, Diemert L, Cohen JE, Bondy SJ, Selby P, Philipneri A, Schwartz R. Estimating the number of quit attempts it takes to quit smoking successfully in a longitudinal cohort of smokers. BMJ Open. 2016 Jun 9;6(6):e011045.

[28] Boakye E, Osuji N, Erhabor J, et al. Assessment of Patterns in e-Cigarette Use Among Adults in the US, 2017-2020. *JAMA Netw Open.* 2022;5(7):e2223266. doi:10.1001/jamanetworkopen.2022.23266.
Owusu D, Huang J, Weaver SR, Pechacek TF, Ashley DL, Nayak P, Eriksen MP. Patterns and trends of dual use of e-cigarettes and cigarettes among U.S. adults, 2015-2018. Prev Med Rep. 2019 Oct 25;16:101009. doi: 10.1016/j.pmedr.2019.101009. PMID: 31763161; PMCID: PMC6861646.

We applaud the scope including "people of all ages across the lifespan," since some federal initiatives have explicitly excluded people over the age of 55 despite this group experiencing the highest morbidity and mortality from smoking and the slowest decline in prevalence.[29] However, on the other end of the age spectrum there is concern regarding the lack of any goals or broad strategies to decrease tobacco use among youth and young adults. To be relevant "for people of all ages across the lifespan" it may not be realistic to separate policies addressing cessation of use and initiation of use for adolescents and young adults, where the boundaries are more fluid between initiation and cessation. In addition, limiting focus to cigarettes is inconsistent with patterns of tobacco use among young people. Many policies that are effective at increasing cessation also decrease initiation. However, the relevance of and evidence base for formal cessation programs in adolescents is much thinner than it is for adults. Thus, a focus only allowing for improving cessation treatment for adolescents while ignoring prevention of initiation may be less effective.

A final suggestion regarding how this framework document considers and addresses "the needs of populations disparately affected by smoking:" In addition to addressing the critical disparities and inequities suffered by sub-populations of people who smoke, including African Americans, American Indians, those with mental health and substance abuse disorders, and those living below the federal poverty line, it may be helpful to also note the existence of intersectional systemic disparities and health inequities that people who smoke, especially those who are dependent, face as a group compared to those who do not smoke.[30] This includes over ten years of lost life expectancy, involuntary addiction usually started during adolescence, exposure to marketing by the tobacco industry that aggressively promotes initiation and ongoing use, continued easy access to a deadly addictive product in "convenience" stores, lack of availability of evidence-based cessation treatment, lack of smokefree living environments, and a century of manipulation by the tobacco industry of societies' institutions, including government and academia, to minimize this devastation and hinder efforts to end it.

Many of the prior 35 surgeon general reports have been devoted to pointing out the burden of suffering that smoking causes to all the people who smoke and who are exposed to second-hand smoke. Continuing to mention this meta-disparity and meta-inequity faced by people who smoke in public health messaging may help maintain broad public support for the policies and practices that will help end smoking's contribution to cancer death in the U.S.

2. Do the broad strategies capture the key components and aspects needed to drive progress toward increasing cessation?

We have suggestions below to improve the broad strategies:

[29] McAfee T, Malone RE, Cataldo J. Ignoring our elders: tobacco control's forgotten health equity issue. *Tobacco Control* 2021;**30:**479-480.

[30] King LM, Barnett TE, Allen AC, Maizel JL, Wilson RE. Tobacco-related health inequalities among Black Americans: A narrative review of structural and historical influences. J Ethn Subst Abuse. 2022 Jul 15:1-31. doi: 10.1080/15332640.2022.2093812. Epub ahead of print. PMID: 35839212.

Goal 2: Increase awareness and knowledge related to smoking and cessation. Cessation education and services should be addressed every time a tobacco policy is being introduced or implemented, and policies should be considered an opportunity to increase cessation behaviors.

Consider adding:

- ***Increase awareness that comprehensive tobacco policies motivate and support cessation****.* Policies such as menthol and flavored tobacco prohibitions significantly increase cessation;[31] numerous studies have found smokefree home policies, including smokefree multiunit housing, increase smoking cessation.[32,33,34] Based on the impact of the menthol ban in Canada, the projected number of smokers who would quit after a US menthol ban would be 790,000 daily smokers (including 200,000 African Americans) and 1,340,000 daily and non-daily smokers (including 381,000 African Americans).[35] Implementation of such a policy should be strongly supported, and implementation should be accompanied by cessation promotion campaigns as well as barrier-free access to cessation services.

- ***FDA action to reduce nicotine in cigarettes to nonaddictive levels will increase cessation.***[36,37,38,39] FDA should enact this policy, and its implementation should be accompanied by campaigns to increase awareness and knowledge to support smoking cessation. It should include all tobacco products.

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[31] Fong GT, Chung-Hall J, Meng G, Craig LV, Thompson ME, Quah ACK, Cummings KM, Hyland A, O'Connor RJ, Levy DT, Delnevo CD, Ganz O, Eissenberg T, Soule EK, Schwartz R, Cohen JE, Chaiton MO. Impact of Canada's menthol cigarette ban on quitting among menthol smokers: pooled analysis of pre-post evaluation from the ITC Project and the Ontario Menthol Ban Study and projections of impact in the USA. Tob Control. 2022 Apr 28:tobaccocontrol-2021-057227.

[32] Borland R, Yong H-H, Cummings KM, Hyland A, Anderson S, Fong GT, 2006. Determinants and consequences of smoke-free homes: findings from the International Tobacco Control (ITC) Four Country Survey. *Tob. Control* 15 (Suppl. 3), iii42–50. 10.1136/tc.2005.012492.

[33] Hyland A, Higbee C, Travers MJ, et al., 2009. Smoke-free homes and smoking cessation and relapse in a longitudinal population of adults. *Nicotine Tob. Res* 11 (6), 614–618. 10.1093/ntr/ntp022.

[34] Haardörfer R, Kreuter M, Berg CJ, et al., 2018. Cessation and reduction in smoking behavior: impact of creating a smoke-free home on smokers. *Health Educ. Res* 33 (3), 256–259. 10.1093/her/cyy014.

[35] Fong GT, Chung-Hall J, Meng G, Craig LV, Thompson ME, Quah ACK, Cummings KM, Hyland A, O'Connor RJ, Levy DT, Delnevo CD, Ganz O, Eissenberg T, Soule EK, Schwartz R, Cohen JE, Chaiton MO. Impact of Canada's menthol cigarette ban on quitting among menthol smokers: pooled analysis of pre-post evaluation from the ITC Project and the Ontario Menthol Ban Study and projections of impact in the USA. Tob Control. 2022 Apr 28:tobaccocontrol-2021-057227. doi: 10.1136/tobaccocontrol-2021-057227.

[36] Benowitz NL, Henningfield JE Reducing the nicotine content to make cigarettes less addictive *Tobacco Control* 2013;**22:**i14-i17.

[37] Dermody SS, Donny EC, Hertsgaard LA, Hatsukami DK. Greater reductions in nicotine exposure while smoking very low nicotine content cigarettes predict smoking cessation. *Tob Control.* 2015;24(6):536–539

[38] . Piper ME, Drobes DJ, Walker N. Behavioral and Subjective Effects of Reducing Nicotine in Cigarettes: A Cessation Commentary. Nicotine Tob Res. 2019 Dec 23;21(Suppl 1):S19-S21. doi: 10.1093/ntr/ntz100. PMID: 31867644; PMCID: PMC6939774.

[39] Hatsukami DK, Luo X, Jensen JA, et al. Effect of Immediate vs Gradual Reduction in Nicotine Content of Cigarettes on Biomarkers of Smoke Exposure: A Randomized Clinical Trial. *JAMA.* 2018;320(9):880–891. doi:10.1001/jama.2018.11473

- ***Link campaigns to increase awareness and knowledge of smoking cessation services such as the quitline with each new tobacco policy*** (e.g., where menthol/flavor bans or clean air laws and policies are implemented, smoking cessation services should be promoted, particularly to people in the communities most affected by new laws and policies)

- ***Promote evidence-based cessation services for priority populations to increase accessibility and acceptability of counseling and FDA-approved pharmacotherapies, as well as integration of cessation best practices into health systems.***

Goal 3: Strengthen and sustain cessation services and supports.

Consider adding:

- ***Strengthen and sustain cessation services including guideline-recommended behavioral counseling and pharmacotherapy and other approaches and supports such as smokefree policies across health care, social services, and institutional settings.*** Health care encompasses primary care, behavioral health, subspecialty care, and acute medical and psychiatric care; social services include homeless shelters, residential drug treatment programs, subsidized housing, while institutional settings include correctional systems and re-entry programs. There is strong evidence that tobacco treatment accompanied with smokefree policies in health care, social services, and behavioral health settings increase smoking cessation.[40] These policies with cessation supports have the greatest impact on increasing cessation behaviors among patients in hospitals, [41] residents in shelters[42], subsidized housing,[43,44] or residential

[40] Hopkins DP, Razi S, Leeks KD, Priva Kalra G, Chattopadhyay SK, Soler RE, et al. Task Force on Community Preventive Services. Smoke-Free Policies to Reduce Tobacco Use: A Systematic Review. American Journal of Preventive Medicine 2010;38(2 Suppl):S275–89.

[41] Frazer K, McHugh J, Callinan JE, Kelleher C. Impact of institutional smoking bans on reducing harms and secondhand smoke exposure. Cochrane Database Syst Rev. 2016 May 27;2016(5):CD011856. doi: 10.1002/14651858.CD011856.pub2. PMID: 27230795; PMCID: PMC10164285.

[42] Martinez J, Jafry MZ, Chen TA, Businelle MS, Kendzor DE, Britton M, Vijayaraghavan M, Reitzel LR. Guest Support for Outdoor Smoke-Free Policies within a Homeless Shelter. Int J Environ Res Public Health. 2022 Feb 19;19(4):2408. doi: 10.3390/ijerph19042408. PMID: 35206595; PMCID: PMC8872137.

[43] Durazo A, Hartman-Filson M, Perez K, Alizaga NM, Petersen AB, Vijayaraghavan M. Smoke-Free Home Intervention in Permanent Supportive Housing: A Multifaceted Intervention Pilot. Nicotine Tob Res. 2021 Jan 7;23(1):63-70. doi: 10.1093/ntr/ntaa043. PMID: 32123908; PMCID: PMC7789947.

[44] Vijayaraghavan M, Benmarhnia T, Pierce JP, White MM, Kempster J, Shi Y, Trinidad DR, Messer K. Income disparities in smoking cessation and the diffusion of smoke-free homes among U.S. smokers: Results from two longitudinal surveys. PLoS One. 2018 Jul 27;13(7):e0201467. doi: 10.1371/journal.pone.0201467. Erratum in: PLoS One. 2018 Nov 21;13(11):e0208153. PMID: 30052671; PMCID: PMC6063424.

drug treatment programs,[45,46] and justice-involved individuals in correctional systems and reentry programs.[47]

- ***Promote continuity of cessation services using a whole person model as individuals from priority populations cycle in and out of health care, social services, and institutional settings.*** A systems-level, quality improvement approach that utilizes disease registries within the electronic health record could increase coordination of tobacco treatment for people interacting with our health and social services systems at different time points.[48,49] Receiving advice to quit and support to quit across different service settings and from multiple providers increases motivation to quit and cessation behaviors. It is critical that cessation treatment receive at least the same level of support as other chronic conditions with significant impacts on morbidity and mortality. This should include reimbursement for services and treatments that is meaningful and consistent with other medical interventions, and not limited by setting or type of provider of services.

- ***Support and encourage partnerships between health systems, pharmacies, and social services to increase delivery of cessation care.*** Providing access to community-based pharmacies to provide cessation services and linking pharmacies to social services settings will increase access to cessation services for populations that are disconnected with medical care. Such approaches have been shown to reduce consumption and increase quit attempts among priority populations.[50,51,52,53]

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[45] McCuistian C, Kapiteni K, Le T, Safier J, Delucchi K, Guydish J. Reducing tobacco use in substance use treatment: An intervention to promote tobacco-free grounds. J Subst Abuse Treat. 2022 Apr;135:108640. doi: 10.1016/j.jsat.2021.108640. Epub 2021 Oct 23. PMID: 34743925; PMCID: PMC8903046.

[46] Marynak K, VanFrank B, Tetlow S, Mahoney M, Phillips E, Jamal Mbbs A, Schecter A, Tipperman D, Babb S. Tobacco Cessation Interventions and Smoke-Free Policies in Mental Health and Substance Abuse Treatment Facilities - United States, 2016. MMWR Morb Mortal Wkly Rep. 2018 May 11;67(18):519-523. doi: 10.15585/mmwr.mm6718a3.

[47] Saloner B, Li W, Flores M, Progovac AM, Lê Cook B. A Widening Divide: Cigarette Smoking Trends Among People With Substance Use Disorder And Criminal Legal Involvement. Health Aff (Millwood). 2023 Feb;42(2):187-196. doi: 10.1377/hlthaff.2022.00901. PMID: 36745833; PMCID: PMC10157835.

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[49] Suen LW, Rafferty H, Le T, Chung K, Straus E, Chen E, Vijayaraghavan M. Factors associated with smoking cessation attempts in a public, safety-net primary care system. Prev Med Rep. 2022 Jan 19;26:101699. doi: 10.1016/j.pmedr.2022.101699. PMID: 35145838; PMCID: PMC8802046.

[50] Hartman-Filson M, Chen J, Lee P, Phan M, Apollonio DE, Kroon L, Donald F, Vijayaraghavan M. A community-based tobacco cessation program for individuals experiencing homelessness. Addict Behav. 2022 Jun;129:107282. doi: 10.1016/j.addbeh.2022.107282. Epub 2022 Feb 16. PMID: 35184003.

[51] De Los Reyes G, Ng A, Valencia Chavez J, Apollonio DE, Kroon L, Lee P, Vijayaraghavan M. Evaluation of a Pharmacist-Linked Smoking Cessation Intervention for Adults Experiencing Homelessness. Subst Use Misuse. 2023 Jul 3:1-9. doi: 10.1080/10826084.2023.2231060. Epub ahead of print. PMID: 37401115.

[52] Shen X, Bachyrycz A, Anderson JR, Tinker D, Raisch DW. Quitting patterns and predictors of success among participants in a tobacco cessation program provided by pharmacists in New Mexico. J Manag Care Spec Pharm. 2014 Jun;20(6):579-87. doi: 10.18553/jmcp.2014.20.6.579. PMID: 24856596.

[53] Hudmon KS, Corelli RL, de Moor C, Zillich AJ, Fenlon C, Miles L, Prokhorov AV, Zbikowski SM. Outcomes of a randomized trial evaluating two approaches for promoting pharmacy-based referrals to the tobacco quitline. J Am

- ***Promote barrier-free access to cessation services.*** HHS should eliminate barriers to access to smoking cessation counseling and pharmacotherapy for those insured by Medicare and managed Medicaid and fee-for-service Medicaid programs. Currently, Medicare does not cover over-the-counter pharmacotherapy for cessation, which is a barrier for smoking cessation for older populations in the United States. HHS should also support policies to ensure over the counter access to all forms of nicotine replacement therapy.

- ***"Working to ensure a baseline level of service for State tobacco quitlines"*** This should include year-round access to evidence-based remotely accessible treatments and support. Examples include supportive coaching/counseling and access to cessation medications, either directly from the quitline or through direct referral relationships with healthcare systems, particularly for patients with cancer.[54,55] Evidence-based digital cessation tools such as texting, tailored interactive websites and apps should be available.

- ***Increase capacity building of tobacco treatment providers across health care and social services, and institutional systems.*** To increase the rapid implementation of cessation services across healthcare, social services, and institutional settings, providers in these sectors need to be trained on how to deliver tobacco treatment.[56,57] Increasing workforce capacity to deliver tobacco treatment will not only increase the diversity of providers who deliver cessation care but will also emphasize that delivering cessation care is a joint responsibility of all providers who interact with individuals who smoke.

- ***Accelerate efforts to assure persons at risk of lung cancer are screened for lung cancer and that lung cancer screening is integrated with smoking cessation services.*** In addition to screening efficacy in identifying early lung cancer, screening

Pharm Assoc (2003). 2018 Jul-Aug;58(4):387-394. doi: 10.1016/j.japh.2018.04.016. Epub 2018 May 18. PMID: 29779983; PMCID: PMC8838875.

[54] Yang MJ, Martínez Ú, Fulton HJ, Maconi ML, Turner K, Powell ST, Chern JY, Brandon TH, Vidrine JI, Simmons VN. Qualitative evaluation of the implementation and future sustainability of an e-referral system for smoking cessation at a US NCI-designated comprehensive cancer center: lessons learned. Support Care Cancer. 2023 Jul 22;31(8):483. doi: 10.1007/s00520-023-07956-4. PMID: 37480364.

[55] Tong EK, Zhu SH, Anderson CM, Avdalovic MV, Amin AN, Diamant AL, Fong TW, Clay B, El-Kareh R, Sankaran S, Bonniot C, Kirby CA, Mayoral A, Sarna L. Implementation, Maintenance, and Outcomes of an Electronic Referral to a Tobacco Quitline Across Five Health Systems. Nicotine Tob Res. 2023 May 22;25(6):1135-1144. doi: 10.1093/ntr/ntad008. PMID: 36977494; PMCID: PMC10202632.

[56] Bialous SA, Nohavova I, Kralikova E, Wells MJ, Brook J, Sarna L. Building capacity in tobacco control by establishing the Eastern Europe Nurses' Center of Excellence for Tobacco Control. Tob Prev Cessat. 2020 Dec 8;6:68. doi: 10.18332/tpc/128190. PMID: 33336120; PMCID: PMC7737564.

[57] Herie M, Connolly H, Voci S, Dragonetti R, Selby P. Changing practitioner behavior and building capacity in tobacco cessation treatment: the TEACH project. Patient Educ Couns. 2012 Jan;86(1):49-56. doi: 10.1016/j.pec.2011.04.018. Epub 2011 May 25. PMID: 21612884.

creates a teachable moment for cessation.[58] Both screening and cessation services save lives and are a powerful, underutilized combination.

Goal 4: Increase access to and coverage of comprehensive, evidence-based cessation treatment.

Consider adding:

- ***Incentivizing health systems, behavioral health settings and social services to adopt universal smokefree policies to promote tobacco cessation in addition to providing tobacco treatment.*** Provision of tobacco treatment when accompanied with smoke-free policies increases short-term and long-term quitting and should be considered the preferred approach among health and social service settings that serve priority populations with high rates of smoking.[59, 60] Individuals with mental health and substance use disorders represent 25% of the nation's population, and yet they consume over 40% of the cigarettes sold in the US.[61] Residential drug treatment facilities, many that are funded by federal agencies, do not have a requirement to implement smoke-free policies despite its known benefit in promoting cessation. HHS agencies that provide funding and support to states and other health entities should consider making some funding contingent on forward progress on both provision of treatment and smokefree policies.

- ***Increase integration of health systems with on-site tobacco treatment and/or quitline services to promote tobacco cessation care.*** The electronic health record in medical and behavioral health settings should be used to integrate evidence-based cessation care through on-site services and/or coordination with quitline services.[62,63]

[58] Deppen SA, Grogan EL, Aldrich MC, Massion PP. Lung cancer screening and smoking cessation: a teachable moment? J Natl Cancer Inst. 2014 May 28;106(6):dju122. doi: 10.1093/jnci/dju122. Erratum in: J Natl Cancer Inst. 2014 Sep;106(9):doi/10.1093/jnci/dju280. PMID: 24872542; PMCID: PMC5073840.

[59] Frazer K, McHugh J, Callinan JE, Kelleher C. Impact of institutional smoking bans on reducing harms and secondhand smoke exposure. Cochrane Database Syst Rev. 2016 May 27;2016(5):CD011856. doi: 10.1002/14651858.CD011856.pub2. PMID: 27230795; PMCID: PMC10164285.

[60] Guydish J, Wahleithner J, Williams D, Yip D. Tobacco-free grounds implementation in California residential substance use disorder (SUD) treatment programs. J Addict Dis. 2020 Jan-Mar;38(1):55-63. doi: 10.1080/10550887.2020.1713687. Epub 2020 Jan 25. PMID: 32186480.

[61] Substance Abuse and Mental Health Services Administration . Adults with mental illness or substance use disorder account for 40 percent of all cigarettes smoked. Rockville: Substance Abuse and Mental Health Services Administration, 2013. Available at: https://ctri.wisc.edu/wpcontent/uploads/sites/240/2017/06/samhsa_factsheet.pdf

[62] Tong EK, Cummins SE, Anderson CM, Kirby CA, Wong S, Zhu SH. Quitline Promotion to Medicaid Members Who Smoke: Effects of COVID-19-Specific Messaging and a Free Patch Offer. Am J Prev Med. 2023 Mar;64(3):343-351. doi: 10.1016/j.amepre.2022.09.009. Epub 2022 Oct 29. PMID: 36319510; PMCID: PMC9617663.

[63] Tong EK, Zhu SH, Anderson CM, Avdalovic MV, Amin AN, Diamant AL, Fong TW, Clay B, El-Kareh R, Sankaran S, Bonniot C, Kirby CA, Mayoral A, Sarna L. Implementation, Maintenance, and Outcomes of an Electronic Referral to a Tobacco Quitline Across Five Health Systems. Nicotine Tob Res. 2023 May 22;25(6):1135-1144. doi: 10.1093/ntr/ntad008. PMID: 36977494; PMCID: PMC10202632.

Goal 5: Expand surveillance of smoking and cessation behaviors and strengthen performance measurement and evaluation.

Consider adding:

- ***Supporting health systems to use a population health and equity-oriented framework using electronic health record data to measure performance, track and eliminate disparities in tobacco prevalence and access to cessation services.*** Health systems should be incentivized to use quality improvement approaches using the electronic health record to improve delivery of cessation services in primary care and behavioral health and acute inpatient settings, track receipt of services, and evaluate the impact of services on cessation behaviors.[64,65]

- ***Develop and strengthen surveillance capacity to track policy adoption both in government as well as private sector.***

Goal 6: Promote ongoing and innovative research to support and accelerate smoking cessation.

Consider adding:

- ***Supporting research on new cessation interventions and/or outreach promotion strategies tailored for populations that have high rates of smoking including African Americans (19.4%), Native American/American Indian (34.9%), sexual gender minorities (25.1%), those with mental health and substance use disorders (27.2%), those living in rural areas, persons experiencing homelessness (70%) and justice-involved populations (50%-60%).[66,67,68]***

- ***Ensure surveillance and evaluation of cessation treatment and community public education campaigns that are aimed at general population of tobacco users are designed with sufficient sample size and with input from priority populations on design to detect differential effects on focus priority populations.***

- ***Support research addressing the impact of policies (such as menthol and flavor bans, nicotine reduction in cigarettes) on smoking cessation utilization and***

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[64] Chung K, Rafferty H, Suen LW, Vijayaraghavan M. System-Level Quality Improvement Initiatives for Tobacco Use in a Safety-Net Health System During the COVID-19 Pandemic. J Prim Care Community Health. 2022 Jan-Dec;13:21501319221107984. doi: 10.1177/21501319221107984. PMID: 35748431; PMCID: PMC9234926.

[65] Cancer Center Cessation Initiative Telehealth Working Group. Telehealth Delivery of Tobacco Cessation Treatment in Cancer Care: An Ongoing Innovation Accelerated by the COVID-19 Pandemic. J Natl Compr Canc Netw. 2021 Nov;19(Suppl_1):S21-S24. doi: 10.6004/jnccn.2021.7092. PMID: 34872049; PMCID: PMC9040141.

[66] Cornelius ME, Loretan CG, Wang TW, Jamal A, Homa DM. Tobacco Product Use Among Adults – United States, 2020. MMWR Morb Mortal Wkly Rep 2022; 71:397-405.

[67] Baggett TP, Tobey ML, Rigotti NA. Tobacco use among homeless people--addressing the neglected addiction. N Engl J Med. 2013 Jul 18;369(3):201-4. doi: 10.1056/NEJMp1301935. PMID: 23863048.

[68] Ahalt C, Buisker T, Myers J, Williams B. Smoking and Smoking Cessation Among Criminal Justice-Involved Older Adults. Tob Use Insights. 2019 Mar 12;12:1179173X19833357. doi: 10.1177/1179173X19833357. PMID: 30890860; PMCID: PMC6416677.

success in priority populations, as well as research that expedites the approval of new cessation treatments.[69]

3. Are there additional goals or broad strategies that should be included in the Framework?

In addition to the six goals and broad strategies identified in the proposed Framework, we suggest adding the following two goals:

- Expand tobacco policies (e.g., menthol and flavor prohibitions, nicotine reduction, retail restrictions, increased taxation, clean air policies) and programs (e.g., strong educational media campaigns about the risks of tobacco use) that increase cessation behavior.

- Integrate an implementation model for tobacco cessation with all tobacco policies.

4. What targeted actions should HHS (Department-wide or within a specific HHS agency) take to advance these goals and strategies?

Add the following actions across four domains:

- ***Increase funding for research:*** Develop funding opportunities to: (1) Identify targeted cessation approaches for priority populations including: African Americans (19.4%), Native American/American Indian (34.9%), sexual gender minorities (25.1%), those with mental health and substance use disorders (27.2%), those living in rural areas, persons experiencing homelessness (70%), and justice-involved populations (50%-60%).[70,71,72] (2) Conduct impact evaluation of health care systems' tobacco cessation services on reach, cessation outcomes, and healthcare costs; (3) Increase the pipeline and diversity of providers who provide cessation care; (4) Comparative effectiveness trials of individually-directed cessation interventions with varying length, combination medications, and counseling approaches with additional supports like contingency management, peer supports and smokefree policies; and (5) Implementation science studies on integration of tobacco policy and cessation approaches

- ***Increase funding for comprehensive tobacco control programs to CDC recommended levels:*** Comprehensive tobacco control programs link cessation with policy but not a single state out of 50 funds these programs at CDC's "recommended"

[69] Rigotti NA, Benowitz NL, Prochaska J, Leischow S, Nides M, Blumenstein B, Clarke A, Cain D, Jacobs C. Cytisinicline for Smoking Cessation: A Randomized Clinical Trial. JAMA. 2023 Jul 11;330(2):152-160. doi: 10.1001/jama.2023.10042. PMID: 37432430; PMCID: PMC10336611.

[70] Cornelius ME, Loretan CG, Wang TW, Jamal A, Homa DM. Tobacco Product Use Among Adults – United States, 2020. MMWR Morb Mortal Wkly Rep 2022; 71:397-405.

[71] Baggett TP, Tobey ML, Rigotti NA. Tobacco use among homeless people--addressing the neglected addiction. N Engl J Med. 2013 Jul 18;369(3):201-4. doi: 10.1056/NEJMp1301935. PMID: 23863048.

[72] Ahalt C, Buisker T, Myers J, Williams B. Smoking and Smoking Cessation Among Criminal Justice-Involved Older Adults. Tob Use Insights. 2019 Mar 12;12:1179173X19833357. doi: 10.1177/1179173X19833357. PMID: 30890860; PMCID: PMC6416677.

level. Only three states (Alaska, California, and Maine) give even 70% of the full recommended amount.[73]

- ***Increase funding for public education campaigns to levels more commensurate with tobacco industry marketing.*** Campaigns by CDC and FDA should be run year-round at high GRP levels rather than for limited periods. Continue and expand messaging and tagging that increases awareness and ease of access to cessation resources. Continue and expand media placement in channels and outlets to ensure reach to tobacco users in focus populations as well as general population of tobacco users.

- ***Improve service delivery in social services and institutional settings****:* Standardize and incentivize service delivery in settings where there are none or piecemeal efforts in cessation such as homeless services, correctional systems, and behavioral health facilities.[74]

- ***Enhance service delivery in primary care and behavioral health settings***: Support integration of tobacco cessation services within a primary care and behavioral health model so that screening, access to cessation services, and measurement of quitting outcomes are coordinated, integrated, and aligned.[75]

- ***Develop reimbursements/incentives:*** Develop reimbursement models so that cessation services can be billed across different service sectors and generate incentivization schemes within health systems to support behavior change.[76,77]

5. What metrics and benchmarks should be included to ensure that the Framework drives progress?

- A decline in smoking prevalence in populations with high prevalence, lack of decline in recent decades, or who have experienced historical tobacco-related inequities including certain racial/ethnic groups, populations with behavioral health conditions, people over

[73] Campaign for Tobacco-Free Kids. Broken Promises to Our Children: The 1998 State Tobacco Settlement 20 Years Later. Washington: Campaign for Tobacco Free Kids, 2018.
[74] O'Brien J, Bonevski B, Salmon A, Oakes W, Goodger B, Soewido D. An evaluation of a pilot capacity building initiative for smoking cessation in social and community services: the Smoking Care project. Drug Alcohol Rev. 2012 Jul;31(5):685-92. doi: 10.1111/j.1465-3362.2012.00464.x. Epub 2012 May 10. PMID: 22571760.
[75] Baxter S, Johnson M, Chambers D, Sutton A, Goyder E, Booth A. The effects of integrated care: a systematic review of UK and international evidence. BMC Health Serv Res. 2018 May 10;18(1):350. doi: 10.1186/s12913-018-3161-3. PMID: 29747651; PMCID: PMC5946491.
[76] Ussher M, Best C, Lewis S, McKell J, Coleman T, Cooper S, Orton S, Bauld L. Financial Incentives for Preventing Postpartum return to Smoking (FIPPS): study protocol for a three-arm randomised controlled trial. Trials. 2021 Aug 2;22(1):512. doi: 10.1186/s13063-021-05480-6. PMID: 34340694; PMCID: PMC8327045.
[77] Tong EK, Stewart SL, Schillinger D, Vijayaraghavan M, Dove MS, Epperson AE, Vela C, Kratochvil S, Anderson CM, Kirby CA, Zhu SH, Safier J, Sloss G, Kohatsu ND. The Medi-Cal Incentives to Quit Smoking Project: Impact of Statewide Outreach Through Health Channels. Am J Prev Med. 2018 Dec;55(6 Suppl 2):S159-S169. doi: 10.1016/j.amepre.2018.07.031. PMID: 30454670.

the age of 55, LGBTQI, people experiencing homelessness and justice-involved populations.

- An increase in policies that support cessation (e.g., clean indoor air laws, taxes) in localities and settings that serve priority populations.

- An increase in population level quit ratio (i.e., former/ever smokers) in priority populations

- Provision of barrier free cessation services in settings that previously lacked them or had minimal access

- Increase in number and diversity of providers who are providing cessation services.

Conclusion:

In summary, the HHS framework provides a good starting pointing to address disparities in access to cessation care, but to truly eliminate disparities and promote equity among disproportionately impacted populations, HHS must include within its framework:

- Comprehensive access to tobacco treatment that is integrated with all tobacco control policies that promote smoking cessation (e.g., clean air policies, menthol and flavored tobacco bans, reduced nicotine content cigarettes, retail restrictions, and minimum price laws)
- Ensure that provision of cessation services is integrated within healthcare systems, institutional and social services settings to ensure that every single individual in the United States who smokes has access to cessation care
- Rapidly expand access to cessation services and smokefree policies in settings that have historically lacked them including behavioral health facilities, criminal legal systems, and homeless services
- Incentivize healthcare systems to use a population health approach to providing cessation care that includes using the electronic health record to deliver cessation services and to track disparities in access to services and cessation outcomes