



Tribal Technical Advisory Group



To the Centers for Medicare & Medicaid Services

c/o National Indian Health Board | 50 F Street NW | Washington, DC 20001 | (202) 507-4070 | (202) 507-4071 fax

December 20, 2024

The Honorable Janet Yellen
Secretary of the Treasury
Department of the Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

The Honorable Julie Su
Acting Secretary of Labor
Department of Labor
200 Constitution Ave NW
Washington, DC 20210

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid
Services
Department of Health & Human Services
7500 Security Blvd
Baltimore, MD 21244

Submitted via regulations.gov

Re: Enhancing Coverage of Preventive Services Under the Affordable Care Act

Dear Secretary Yellen:

On behalf of the CMS Tribal Technical Advisory Group (TTAG), I write to provide a response to the proposed rule, *Enhancing Coverage of Preventative Services Under the Affordable Care Act*, offered by the Departments of Treasury, Labor, and Health & Human Services' (HHS) Center for Medicare and Medicaid Services (CMS). TTAG's leadership supports the Departments' proposed rule to provide for a separate exceptions process for preventive treatments and services per the requirements of the Public Health Service Act, section 2713; to require plans and issuers to disclose to participants, beneficiaries, or enrollees about their policies regarding coverage of preventive treatment and services, including an exceptions request process, and the coverage of preventive over the counter (OTC) products and treatments, including contraceptive items, without a prescription and without cost sharing.

Too often, individuals are unaware of benefits available to them, limiting their access to preventative services, and preventive services, products, and treatments that are key to improving health disparities for all types of health conditions. This proposal supports access to medically necessary preventive services for all patients and recognizes the importance of preventive services and products to women's health care, including access to readily available and affordable OTC contraceptive items. Our Tribal leadership supports the expansion of OTC preventive products coverage to a wider set of OTC preventive products.

The Indian health system¹ exists to meet the federal treaty and trust obligations to provide health care to Tribal Nations and their citizens. This system, however, has been deeply underfunded which, along with historic removal and terminations policies, has resulted in the highest levels of disparities for most health conditions for American Indian and Alaska Native peoples. The Indian health system is funded well below its level of need, operating on only \$4,078 of spending per capita, while the national average spending per user was \$13,493. Due to this disparity, Indian healthcare providers rely on third party billing to close the gap in care and services and rely on the provisions of the Public Health Service Act Section 2713 to provide for full coverage and reimbursement of preventive care. Below, the CMS TTAG provides comments and recommendations on this proposed rule.

RECOMMENDATIONS:

1. Reasonable Medical Management of Recommended Preventive Services: Exceptions Process

Coverage of preventive services is critical to the prevention or progression of chronic conditions and preventing many emergent conditions, which improve outcomes and reduce disparities in our communities. We know that these preventive services and products close the gap because we already have examples in the Indian health system through the Special Diabetes Program for Indians (SDPI). The SDPI is the only program that has produced a downward trend in instances of diabetes and pre-diabetes.² In the Indian health system we understand the value of preventive care.

While members of federally recognized Tribes are exempt from cost-sharing and co-payments under the ACA at section 1402(d)(1), coverage of preventive services is still a critical component of healthcare coverage for American Indian and Alaska Native beneficiaries, particularly when an individual is referred to or elects to seek care from non-Indian providers. Promoting enhanced access to preventive services, products, and treatments is key, and the Departments' renewed attention to these coverage issues and the proposal to provide for an exceptions process to ensure preventive services are not only available but also meet the medical necessities of the individual will help close the gaps for our communities.

We agree with the Departments' decision to make the exceptions process in this rule applicable to all preventive services, products, and treatments. TTAG generally agrees with the framework identified by the Departments in the rule, and TTAG encourages the Departments to require a separate, expedited appeals process for the exception request

¹ The Indian health system is comprised of the Indian Health Service (IHS), Tribes and Tribal organizations, and urban Indian organizations which all provide care to eligible American Indian and Alaska Native individuals.

² Indian Health Service, "Special Diabetes Program for Indians 2020 Report to Congress". Accessed 12/13/2024
(https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/documents/SDPI2020Report_to_Congress.pdf).

pathway to ensure that if an exception request is denied, providers and patients are not left without recourse. Further to the Departments' question on requirements which plans and issuers might place on documentation for the exception requests, TTAG recommends that such documentation be reliant, in part, on provider attestation based on professional assessment of individual patients and their medical history.

The TTAG urges HHS and CMS to ensure that not only commercial insurances, Medicare Part D plans, pharmacy benefits managers, and other commercial plans and issuers follow these preventive care coverage rules, but to also ensure that State Medicaid plans and contractors are also compliant with the coverage and provisions of medically necessary exceptions for preventive services, products, and treatments.

We further address some of the Departments' specific questions below.

- *The Departments request comment on how plans and issuers could ensure that this information is readily available and accessible, such as any specific formats, mechanisms, or other best practices that could promote access to information about the exceptions process.*

TTAG's leadership supports a plan or issuer being required to provide a website link or landing page link to make information about the plan's or policy's preventive services, products, and treatments coverage readily available and in easily identifiable locations. Information available to patients should include a summary of the final rule outlining a plan's or issuer's requirements to provide no-cost sharing coverage for preventive items, a summary of patient's rights for exception waiver requests, and the process a provider, patient, or their designated representative should follow to secure such a medically necessary exception for preventive services, products, or treatment. Issuers and plans should also be required to provide more tailored cost and benefit information to participants, beneficiaries, or enrollees when they provide other relevant plan documents, such as drug formularies or Summaries of Benefits and Coverage (SBCs).

Information available online must be easy to understand and be written at the national average reading level (7th to 8th grade) and it would be helpful to have an FAQ available to answer reoccurring questions. The website or landing page should also include a phone line individuals can contact if they would like to request additional information.

Issuers or plans can also notify individuals of the policy's coverage through mail. This would support individuals with limited broadband access. The letter should also include a summary of the final rule, summary of patient's rights, the process a provider, patient, or their designated representative should follow to secure such a medically necessary exception for preventive services, products, or treatment, and common FAQs.

If available, plans and issuers should utilize their Tribal liaisons to relay this information to IHS Service Units, Tribal operated clinics, and urban Indian health clinics. This information can be shared through email, mail, or meetings. For example, Washington State's Department of Health, Health Care Authority hosts a Monthly-Tribal-Meeting with

Managed Care Organizations and Indian healthcare providers where this information could be shared. By ensuring this information reaches trusted community partners then the populations most in need can be made aware of this policy coverage.

- *The Departments request comment on the extent to which plans and issuers currently make such information available and accessible and to whom (for example, to prospective and current participants, beneficiaries, and enrollees and their providers), whether any additional individuals or groups should have access to this information if this proposal is finalized, and whether the Departments should finalize more specific standards regarding transparency or accessibility of information about the exceptions process in regulation.*

When the rule is finalized, issuers or plans can notify targeted populations through mail and email. Information available to this population should also include a summary of the final rule, summary of patient's rights, the process a provider, patient, or their designated representative should follow to secure such a medically necessary exception for preventive services, products, or treatment, and FAQs.

The Department of Health and Human Services and CMS should consider releasing a news release on the final rule with the same information listed above. Further, this information should be permanently hosted on CMS's webpages on the legal requirements for coverage for preventative care and services by health plans and issuers. This will support individual's knowing their rights.

2. Coverage of OTC Preventive Products – Contraceptive items

The TTAG appreciates the Departments for discussing the coverage of OTC Preventive Products following their initial OTC Preventive Products Request for Information conducted in late 2023. While we appreciate the Departments' considerations of what preventive products to require coverage of in the proposed rule, we believe that the proposal to require coverage of only OTC contraceptive items to be too narrow for an initial coverage requirement.

We agree that OTC contraceptive items are critical to women's health care and should be covered, as this will improve American Indian and Alaska Native women's access to critically important preventive care products that can improve health care outcomes for women, mothers, and their infants. AI/AN women experience some of the greatest disparities to access care and have the highest maternal mortality rates in the country. For example, AI/AN mothers are 2.3 times more likely to die from pregnancy-related causes compared to non-Hispanic white women;³ 11.6 percent of non-Hispanic AI/AN

³ Petersen EE, Davis NL, Goodman D, et al. Racial/Ethnic Disparities in Pregnancy-Related Deaths – United States, 2007-2016. MMWR Morb Mortal Wkly Rep 2019;68:762-765. DOI: <http://dx.doi.org/10.15585/mmwr.mm6835a3>

infants are born preterm;⁴ and non-Hispanic AI/AN infants have 1.8 times the rate of post neonatal infant mortality compared to non-Hispanic white infants.⁵

Our communities, however, suffer from significant other health disparities which would benefit from the required coverage of OTC preventive care products. As part of the proposed rule, the Departments ask if other OTC preventive products should be covered and note the factors the Departments weighed in drafting the proposed rule. We agree that requiring all OTC preventive products would be difficult to implement effectively. Our Tribal leadership recommend that the Departments additionally require a limited set of OTC Preventive Products which are linked to the top three to five preventable chronic diseases to support improved access to preventive care and products.

TTAG further addresses specific questions from the Departments below, noting our recommendation to cover a broader set of OTC preventive products.

(1) In-Network and Out-of Network coverage of OTC Preventive Products

- *Specifically, the Departments request comment on whether plans or issuers should be required to cover the non-preferred version without cost-sharing requirements at the in-network pharmacy, without requiring the consumer to pursue an exceptions process when a preferred version is unavailable at an in-network pharmacy. The Departments also request comment on whether and how plans and issuers should document the unavailability of a preferred OTC contraceptive for coverage purposes.*

TTAG leaderships encourages the Department to require plans or issuers to cover the non-preferred version without cost-sharing requirements at the in-network pharmacy, without requiring the consumer to pursue an exceptions process when a preferred version is unavailable. This would be especially helpful for communities in rural areas, where a preferred version may not be available or when a stock of a preferred version is delayed or unavailable. To document the unavailability of a preferred OTC preventive product, plans should accept a claim with a note in the comment section on the reasoning why a non-preferred version was procured. Plans and issuers should notify their staff who process claims, to review the comments and approve these claims.

B. Communicating OTC Preventive Product Coverage Requirements

- *The Departments also request comment on whether plans and issuers should have the option to include in the statement either a phone number or an internet link—rather than both—to where a participant, beneficiary, or enrollee can learn more about the plan's or policy's contraception coverage. The Departments are interested in better understanding the benefits and burdens associated with each approach.*

⁴ Osterman M, Hamilton B, Martin JA, Driscoll AK, Valenzuela CP. Births: Final Data for 2020. Natl Vital Stat Rep. 2021; 70 (17): 1-50. Retrieved at <https://pubmed.ncbi.nlm.nih.gov/35157571/>

⁵ Ely DM, Driscoll AK. Infant mortality in the United States, 2021: Data from the period linked birth/infant death file. National Vital Statistics Reports; vol 72 no 11. Hyattsville, MD: National Center for Health Statistics. 2023. DOI: <https://dx.doi.org/10.15620/cdc:131356>.

TTAG leadership encourages the Department to require plans and issuers to provide a phone number and internet link for patients to learn more about the plan's or policy's preventive product coverage. This can be a line that is already maintained by the plan or issuer. As noted above, some Native communities have limited access to broadband and to ensure equitable outreach is provided, a number must be provided to all individuals.

- *The Departments also request comment on whether plans and issuers should be required to include in this statement the general names or types of OTC contraceptive items that are covered without a prescription and without cost sharing (for example, "daily oral contraceptive," "Plan B (levonorgestrel)," or "condoms"). Under this approach, users would not need to call the provided phone number or navigate to the linked web page and could simply copy and paste the provided product names into the self-service tool's search field to find local pharmacies where they can access the product without a prescription and without cost sharing.*

TTAG's leadership supports plans and issuers being required to include a list of items available without a prescription and without cost sharing in the statement. On the website or landing page a plan or issuer is required to have; it would be appropriate for a list of general names or types of OTC preventive products that are covered to be listed on the site. However, it is critical for the plan or issuer to still provide a link or phone number for individuals to contact.

CONCLUSION

We appreciate the Department of the Treasury, Department of Labor, and the Department of Health and Human Services' Centers for Medicare and Medicaid Services for considering the exceptions for medically necessary preventive services, products, treatments and expansion of access to OTC preventive products. These recommendations, if accepted, will be of great benefit to Native and non-Native populations alike.

Sincerely,

A handwritten signature in black ink, reading "W. Ron Allen". The signature is fluid and cursive, with the first name "W." and last name "Allen" clearly distinguishable.

W. Ron Allen, CMS TTAG Chair
Jamestown S'Klallam Tribe, Chairman/CEO