IHS TRIBAL SELF-GOVERNANCE ADVISORY COMMITTEE

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Submitted via: www.regulations.gov

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Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Comments on Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P)

Dear CMS Official:

I write on behalf of the Indian Health Service (IHS) Tribal Self-Governance Advisory Committee (TSGAC) to comment on the Proposed Rule titled, "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program".

The Proposed Rule would revise Medicare Part C and Part D regulations to implement certain provisions of the Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act. In addition, the Proposed Rule seeks to improve program quality, accessibility, and affordability; improve the CMS customer experience; and address program integrity policies related to payments based on prescriber, provider, and supplier status. The Proposed Rule also would update the official Part D electronic prescribing standards, as well as clarify program requirements and certain technical changes regarding treatment of Part A and Part B appeal rights related to premium adjustments.

The TSGAC has concerns about the effect of the Proposed Rule on low-income American Indian and Alaska Native (Al/AN) Medicare beneficiaries. Under current Medicare Part D regulations, individuals dually eligible for Medicare and Medicaid or eligible for the Low-Income Subsidy (LIS) program qualify for a special enrollment period (SEP) that allows them to enroll in, switch, or disenroll from prescription drug plans (PDPs) at any time.¹ The Proposed Rule would limit the use of this Part D SEP for dual-eligible and LIS-eligible Medicare beneficiaries. For Al/AN Medicare beneficiaries, this could have the effect of blocking access to critically needed pharmaceuticals or, at a minimum, denying eligibility for reimbursement for these pharmaceuticals for a period of time.

¹ See 42 CFR 423.38(c)(4).

Discussion

Under the Proposed Rule, CMS would revise 42 CFR 423.38(c) to limit use of the Medicare Part D SEP for dual-eligible or LIS-eligible beneficiaries as follows:

- Add a new paragraph (c)(4)(i), under which most dual-eligible or LIS-eligible beneficiaries could use the Part D SEP only once per calendar year; and,
- Add a new paragraph (c)(4)(ii), under which dual-eligible or LIS-eligible beneficiaries assigned to a PDP by CMS or a state could only use the Part D SEP before that election becomes effective or within 2 months of their enrollment in the plan.²

Further, the Proposed Rule would make the Part D SEP unavailable for dual-eligible or LIS-eligible beneficiaries if their current PDP labels them as "at-risk" or "potentially at-risk" for substance abuse, meaning that they could not switch plans or disenroll from the plan. This restriction on using the Part D SEP would remain in place until the plan removed the "at-risk" or "potentially at-risk" designation. If the plan identifies a dual-eligible or LIS-eligible beneficiary as "potentially at-risk," that designation would expire in 90 days if the plan does not subsequently designate the beneficiary as "at-risk." If the plan does subsequently designate the beneficiary as "at-risk," that designation would remain in place until: 1) the plan removes the designation based on a future determination; or, 2) after 12 months; whichever is sooner.

In contrast to the arguments made in putting forth the Proposed Rule, maintaining maximum flexibility regarding enrollment in Medicare Part D and the ability to change PDPs best serves the interests of low-income beneficiaries, especially AI/AN beneficiaries.

In the Proposed Rule, CMS noted that it supports the "underlying principle that LIS beneficiaries should have the ability to make an active choice" in electing PDPs. Yet, the proposed limits on the use of the Part D SEP would severely curtail this ability for dual-eligible or LIS-eligible Medicare beneficiaries who might have otherwise benefited from switching plans. In addition, as only a small subset of dual-eligible or LIS-eligible Medicare beneficiaries opt to use the Part D SEP each year (fewer than 10 percent in 2016, per CMS), the concerns cited in the Proposed Rule about allowing the current policy to continue seem unwarranted.

² The proposed rule also would add a new paragraph (c)(9), under which all Medicare beneficiaries who have a change in their Medicaid or LIS-eligible status could use a new SEP to make an election within 2 months of the change, or of receiving notification of the change, whichever is later.

³ The Proposed Rule would define an "at-risk beneficiary" as an individual who is eligible for Medicare Part D, identified by clinical guidelines, and determined "to be at-risk for misuse or abuse of such frequently abused drugs under a Part D plan sponsor's drug management program." The Proposed Rule would define a "potentially at-risk beneficiary" as an individual who is eligible for Part D, identified by clinical guidelines, and with respect to whom a "Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as a potential at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification." See proposed 42 CFR 423.100.

With regard to Indian Health Service (IHS) beneficiaries in particular, inserting the Medicare Part D drug plans into the relationship between Medicare/IHS beneficiaries and their IHS/Tribal providers is not helpful. IHS and Tribal health programs assist IHS beneficiaries in coordinating the delivery of needed health care services, including the provision of pharmaceutical services. Inserting the Part D drug plans into the decision-making process as to whether a low-income IHS beneficiary can switch plans—a decision often made in order to access a specific prescription drug or access the prescription drug at a more affordable cost—is unnecessary and would disrupt the patient-provider relationship.

To best meet the needs of low-income Medicare beneficiaries and the needs of IHS beneficiaries in particular, CMS should continue to allow these beneficiaries to have the ability to enroll in or switch plans based on their individual needs as provided under current law.

Recommendation

In response to the concerns outlined above, the TSGAC requests that CMS, in finalizing the Proposed Rule, drop the proposals to limit the use of the Medicare Part D SEP for dual-eligible and LIS-eligible beneficiaries. Alternatively, if CMS intends to retain these provisions, the TSGAC requests that the agency specify an exemption for IHS-eligible persons.⁴

<u>Conclusion</u>

Thank you for the opportunity to provide these comments on the Proposed Rule. In the future, we encourage CMS to engage with Tribes prior to the release of proposed rules, such as this one, which would have a significant impact on Al/ANs. If you have any questions or wish to discuss these comments further, please contact me at (860) 862-6192 or via email at lmalerba@moheganmail.com.

Sincerely,

Marilynn "Lynn" Malerba

Lynn Malecta

Chief, The Mohegan Tribe of Connecticut

Chairwoman, Tribal Self-Governance Advisory Committee

cc: Kitty Marx, Director, Division of Tribal Affairs/IEAG/CMCS

Jennifer Cooper, Acting Director, Office of Tribal Self-Governance, IHS

TSGAC Members and Technical Workgroup

⁴ Under section 1311(c)(6)(D) of the Affordable Care Act, certain IHS-eligible persons enrolled in health insurance coverage through a Marketplace likewise are able to enroll in, switch, or disenroll from plans at any time throughout the year.