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February 19, 2019

Seema Verma
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-9926-P
P.O. Box 8016
Baltimore, MD
21244-8016

RE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020

Dear Administrator Verma:

On behalf of the Centers for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Group (TTAG),<sup>1</sup> I write to submit comments on the proposed rule published in the Federal Register on January 24, 2019: "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020," (CMS-9926-P) (proposed rule or payment rule).

The TTAG has previously submitted comments responding to proposed rules related to health insurance marketplaces in the ACA and have an impact Indian Country. This letter therefore incorporates by reference the letters submitted by the TTAG and the National Indian Health Board (NIHB) from the years 2015, 2016, 2017, and 2018.<sup>2</sup> Here, the TTAG will also take a position on "silver loading," a practice that has indirect impact on Indian Country. "Silver

2016-09-29c.pdf; Comments on CMS-9937-P; Notice of Benefits and Payment Parameters for 2017 (Dec. 21, 2015), <a href="https://www.nihb.org/tribalhealthreform/wp-content/uploads/2015/12/TTAG-Comment-on-CMS-9937-P.pdf">https://www.nihb.org/tribalhealthreform/wp-content/uploads/2015/12/TTAG-Comment-on-CMS-9937-P.pdf</a>.

<sup>&</sup>lt;sup>1</sup> The TTAG advises CMS on Indian health policy issues involving Medicare, Medicaid, the Children's Health Insurance Program, and any other health care programs funded (in whole or part) by CMS. In particular, TTAG focuses on providing policy advice to CMS regarding improving the availability of health care services to American Indians and Alaska Natives (AI/ANs) under these federal health care programs, including through providers operating under the health programs of the Indian Health Service (IHS), Tribes, Tribal organizations, and Urban Indian organizations (I/T/Us or Indian health care providers).

<sup>&</sup>lt;sup>2</sup> National Indian Health Board (NIHB), Comments on Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment (CMS10401/OMB control number 0938-1155) (Mar. 9, 2018), <a href="https://www.nihb.org/tribalhealthreform/wp-content/uploads/2018/03/TTAG-Comment-on-CMS-1041-with-header.pdf">https://www.nihb.org/tribalhealthreform/wp-content/uploads/2018/03/TTAG-Comment-on-CMS-1041-with-header.pdf</a>; Patient Protection and Affordable Care Act; Market Stabilization Proposed Rule (CMS-9929-P) Comment (Mar. 7, 2017), <a href="https://www.nihb.org/tribalhealthreform/wp-content/uploads/2017/03/TTAG-ACA-Market-Stabilization-PR-Comment-2.pdf">https://www.nihb.org/tribalhealthreform/wp-content/uploads/2016/10/NIHB-comments-on-CMS-9934-P-</a>. Notice of Benefit and Payment Parameters for 2018 (CMS-9934-P) (Oct. 6, 2016), <a href="https://www.nihb.org/tribalhealthreform/wp-content/uploads/2016/10/NIHB-comments-on-CMS-9934-P-">https://www.nihb.org/tribalhealthreform/wp-content/uploads/2016/10/NIHB-comments-on-CMS-9934-P-</a>

loading" or "actuarial loading" occurs where insurers increase Cost Sharing Reduction (CSR)-related premium rates only on silver level plans due to the absence of Congressional appropriations to fund CSRs.<sup>3</sup> This letter will also address concerns related to notice and oversight of mid-year formulary changes on prescription drugs.

## Background - Indian health system

Section 10221 of the Patient Protection and Affordable Care Act (ACA) permanently reauthorized the Indian Health Care Improvement Act (IHCIA). The IHCIA serves as the statutory foundation for the provision of health care to American Indians and Alaska Natives (AI/ANs) through the Indian Health Services, Tribes and Tribal organizations, and Urban Indian programs (I/T/U). The preservation of the IHCIA is essential for the continued provision of health care to the AI/AN population. Thus, any changes to or repeal of the ACA or reductions to the Medicaid program would have significant negative impacts on the Indian health system.

There are a number of provisions within the ACA separate from the IHCIA that have significant implications for the Indian health system.<sup>4</sup> To assist AI/ANs in accessing health care services when enrolled in health insurance through the Marketplace, the ACA established Indian-specific cost-sharing protections, under which AI/ANs who meet the ACA's definition of Indian pay no deductibles, coinsurance, or copayments when receiving essential health benefits.<sup>5</sup> AI/ANs can enroll in either a zero or limited cost-sharing plan, depending on their income level. The ACA also prohibits health insurers from reducing payments to Indian health care providers (IHCPs) by the amount of any cost-sharing that AI/ANs would have owed without these protections. Until October 2017, the federal government reimbursed insurers for the cost of providing \$0 cost-sharing to eligible Native American enrollees.

### **ACA Marketplace changes**

On October 12, 2017, the Trump Administration announced that it planned to stop the government's reimbursement of cost-sharing reduction (CSR) payments made to health

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<sup>&</sup>lt;sup>3</sup> Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020 (84 FR 227) at 227-321 (Jan. 24, 2019), <a href="https://www.federalregister.gov/documents/2019/01/24/2019-00077/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2020">https://www.federalregister.gov/documents/2019/01/24/2019-00077/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2020</a>.

<sup>&</sup>lt;sup>4</sup> Special Enrollment Periods (Section 1311) – Provide for special monthly enrollment periods for Indians and their dependents; Cost Sharing Reductions (Section 1402, Section 2901) – Eliminates all cost-sharing for Indians under 300% of the federal poverty level (FPL) enrolled in any individual market plan offered through a federal or state Exchange. Establishes that Indian beneficiaries enrolled in a qualified health plan (QHP) are not charged cost-sharing for any item or service provided directly by I/T/U or through referral under contract health services; Exemptions (Section 1501) – Exempt members of Indian Tribes from the shared responsibility penalty for failure to comply with the requirement to maintain minimum essential coverage; Payer of Last Resort (Section 2901) – Establishes that I/T/U providers are the payers of last resort for services provided to Indians by I/T/U for services provided through such programs; Tax Exclusions for Health Benefits (Section 9021) – Excludes the values of health benefits provided or purchased by the Indian Health Service, Tribes, or Tribal organizations from gross income.

<sup>&</sup>lt;sup>5</sup> Tribal Self Governance Advisory Committee, American Indian and Alaska Native (AI/AN) Marketplace Enrollment and Cost-Sharing Payments, as of December 2016 (Mar. 20, 2017), <a href="https://www.tribalselfgov.org/wp-content/uploads/2017/03/TSGAC-Memo-AI-AN-Marketplace-Enrollment-CSRs-2016-2017-03-20b.pdf">https://www.tribalselfgov.org/wp-content/uploads/2017/03/TSGAC-Memo-AI-AN-Marketplace-Enrollment-CSRs-2016-2017-03-20b.pdf</a>.

insurers that participated in the ACA's Health Insurance Marketplaces (Marketplace). The announcement meant that the Administration would cease making payments for premium subsidies for low-income individuals who purchased Marketplace plans created by the ACA. The announcement of the termination of CSR premium payments coincided with Executive Order 13813, which instructed federal agencies to expand access to association health plans ("AHPs"); short-term, limited-duration insurance ("STLDI"); and health reimbursement arrangements ("HRAs").

### **Silver Loading**

The proposed rule seeks comments on "ways in which HHS might address silver loading, for potential action in future rulemaking applicable not sooner than plan year 2021." Further, the Administration "supports a legislative solution that would appropriate CSR payments and end silver loading." Silver loading is the result of Congress not appropriating funds to pay CSRs, with the result being an increase to the premiums of benchmark plans used to calculate premium tax credits.

It is estimated that more than 27,000 AI/ANs are enrolled in the Marketplace. Silver loading has been formulated by issuers as a method to address high premiums and stabilize the Marketplace. Since CSRs help make the Marketplace affordable for this population, any action by CMS that stands to make insurance through the Marketplace no longer affordable will either cause the Marketplace to collapse or cause AI/ANs to leave the Marketplace. This would effectively eliminate the option for the population to have affordable health care. The TTAG supports keeping the Marketplace stable so that health coverage is affordable for AI/ANs, and thus encourages CMS to continue to mitigate instability in the Marketplace. The TTAG recommends that CMS continue to allow issuers to silver load until a legislative solution is achieved by Congress. In addition, the TTAG recommends that silver loading remain an option to improve affordability and attract issuers and enrollees to the Marketplace.

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<sup>&</sup>lt;sup>6</sup> Presidential Executive Order Promoting Healthcare Choice and Competition Across the United States (Oct. 12, 2017), <a href="https://www.whitehouse.gov/presidential-actions/presidential-executive-order-promoting-healthcare-choice-competition-across-united-states/">https://www.whitehouse.gov/presidential-actions/presidential-executive-order-promoting-healthcare-choice-competition-across-united-states/</a>.

<sup>&</sup>lt;sup>7</sup> Language of proposed rule at 283:

Silver Loading – Section 1402 of the PPACA requires issuers to provide CSRs to help make coverage affordable for certain low- and moderate-income consumers who enroll in silver level QHPs, as well as Indians who enroll in QHPs at any metal level. Section 1402 of the PPACA further states that HHS will reimburse issuers for the cost of providing CSRs.

<sup>&</sup>lt;sup>8</sup> NIHB, Health Care Alert: In the Last 24 Hours President Trump Orders Two Actions on the Affordable Care Act-Potentially Heavy Impacts on American Indian/Alaska Native Health (Oct. 13, 2017), <a href="http://campaign.r20.constantcontact.com/render?m=1110714960954&ca=0246ad30-566f-43f0-af67-159fdf67e5b7">http://campaign.r20.constantcontact.com/render?m=1110714960954&ca=0246ad30-566f-43f0-af67-159fdf67e5b7</a>.

# Mid-year formulary changes

In response to the American Patients First blueprint unveiled last year,<sup>9</sup> the proposed rule also proposes allowing individual, small group, and large group market health insurance issuers to adopt mid-year formulary changes to incentivize greater enrollee use of lower-cost generic drugs.<sup>10</sup> In addition, the payment rule proposes changes to requirements for how issuers and self-insured group health plans treat cost sharing for brand-name drugs when a generic equivalent is available. With respect to Medicare Part D, the United States Government Accountability Office has reported that mid-year changes affect sponsors' plan formularies and may disrupt beneficiaries' access to certain prescription drugs or make them responsible for new or unexpected costs.<sup>11</sup>

The TTAG shares the GAO's concern as related to the ACA payment rule. We are also concerned that if the proposed rule is implemented, Marketplace plans will be in favor of lowering the user fee and switching pharmacy benefits mid-year. As the proposed rule itself states:

"We also recognize that some consumers may have concerns about the impact this proposed change may have, given that consumers often purchase a plan based on the plans' prescription drug coverage. However, we believe these concerns may

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- (5) For plan years beginning on or after January 1, 2020, a group health insurance issuer may make the following mid-year formulary changes, to the extent permitted by applicable State law: It may add a generic equivalent to a formulary within a reasonable time after the generic equivalent becomes available, and, if it does so, it may remove the equivalent brand drug or drugs from the formulary or move the equivalent brand drug or drugs to a higher formulary drug tier. If the issuer makes any such changes:
- (i) The issuer must notify plan enrollees in writing a minimum of 60 days prior to making the changes. This notice must identify the name of the brand drug that is the subject of the change, disclose whether the brand drug will be removed from the formulary or placed on a different cost-sharing tier, provide the name of the generic equivalent that will be made available, specify the date the changes will become effective, and state that under the appeals processes outlined in § 147.136 of this subchapter or the exceptions processes outlined in § 156.122(c) of this subchapter, enrollees and dependents may request and gain access to the brand drug when clinically appropriate and not otherwise covered by the health plan. Proposed rule at 313.

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We solicit comments on whether a different advance notice period would be more appropriate, such as 90 days or 120 days." Proposed rule at 235.

<sup>&</sup>lt;sup>9</sup> Fact Sheets: President Donald J. Trump's Blueprint To Lower Drug Prices (May 11, 2018), <a href="https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/">https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/</a>
<sup>10</sup> From the proposed rule:

<sup>&</sup>quot;The proposed changes to 45 CFR parts 146, 147, and 148 would allow issuers, beginning with plan years on or after January 1, 2020, to update their prescription drug formularies by allowing certain mid-year formulary changes, subject to applicable state law, in an effort to optimize the use of new generic drugs as they become available. Proposed rule at 234.

<sup>&</sup>lt;sup>11</sup> GAO, Medicare Part D Formularies: CMS Conducts Oversight of Mid-Year Changes; Most Mid-Year Changes Were Enhancements (June 30, 2011), <a href="https://www.gao.gov/products/GAO-11-366R">https://www.gao.gov/products/GAO-11-366R</a>.

be alleviated given the addition made to the formulary of the generic equivalent, which would *generally* be more affordable (emphasis added)."<sup>12</sup>

The proposed rule's changes come at the expense of the beneficiary and is not be in the best interest of the consumers. The prospect of formulary changes is a consumer protection issue, since insurers' ability to switch plans and prescription drugs without adequate notice to the beneficiary is to the detriment of the consumer. The Administration has asked whether advanced notice should number 120 days. The TTAG agrees that notice should be provided with a minimum of 120 days, but advocates that mid-formulary changes be prohibited by this rule.

Soliciting Tribal feedback on the ACA is consistent with the federal government's recognition of Tribal governments as sovereign nations, to which the U.S. has treaty obligations and trust responsibilities. Trust and treaty obligations to Tribes are rooted in the U.S. Constitution, numerous treaties, federal statutes, agency regulations, executive orders, and judicial decisions. This trust and treaty relationships provide the basis for the federal government's obligation to furnish American Indians with a variety of services based on their political status as Indians—including the provision of health care. Moreover, the special government-to-government political relationship between the U.S. and Tribes distinguishes Indians from any racial classification in the affirmative action laws and in the application of other federal statutes that establish federally funded programs for the general public. 16

#### **Conclusion**

We thank you for the opportunity to provide comments and recommendations on the ACA Payment Parameters for 2020, and look forward to further engagement. TTAG believes it is incumbent on CMS to take action on stabilizing the Marketplace; and to provide dedicated funding for outreach, marketing, and education during open enrollment periods. The TTAG stands ready to answer any questions or provide technical assistance that CMS may have.

Best regards,

W. Ron Allen, Chair

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Tribal Technical Advisory Group

<sup>&</sup>lt;sup>12</sup> Proposed rule at 235.

<sup>&</sup>lt;sup>13</sup> *See supra* note 10, at 234.

<sup>&</sup>lt;sup>14</sup> Indian Health Service, Basis for Health Service,

https://www.ihs.gov/newsroom/factsheets/basisforhealthservices/.

<sup>&</sup>lt;sup>15</sup> See Exec. Order No. 13175, Consultation and Coordination With Indian Tribal Governments, 65 Fed. Reg. 67249 (Nov. 9, 2000), <a href="https://www.federalregister.gov/documents/2000/11/09/00-29003/consultationand-coordination-with-indian-tribal-governments">https://www.federalregister.gov/documents/2000/11/09/00-29003/consultationand-coordination-with-indian-tribal-governments</a>.

<sup>&</sup>lt;sup>16</sup> HHS Tribal Consultation Policy at 1–2 (2010),

https://www.hhs.gov/sites/default/files/iea/tribal/tribalconsultation/hhs-consultation-policy.pdf; CMS Tribal Consultation Policy at 1 (2011), <a href="https://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/Downloads/CMSTribalConsultationPolicy2015.pdf">https://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/Downloads/CMSTribalConsultationPolicy2015.pdf</a>.