

Department of Health

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May 28, 2025

Re: Tribal Consultation for Pharmacy Dispensing Fee SPA

Dear Tribal Health Leaders

Thank you for your comments on the Pharmacy Dispensing Fee State Plan Amendment consultation. The department would like to respond to your comments and thank you again for your engagement in the Tribal consultation process.

<u>Tribal Comment #1 – Alaska Native Health Board (ANHB)</u>

ANHB agrees with the Department that any process delays in implementing a new SPA and regulatory package that would result in reverting to the pre-Pandemic dispensing fee rate should be avoided. ANHB agrees as well that the dispensing fee should be set using an objective, data-driven approach. However, it defies both logic and the lived experience of Tribal pharmacy providers that the cost of dispensing would have gone down between 2019 and 2024. Moreover, the Department's manipulation of the survey results artificially and arbitrarily reduced the proposed rates. Therefore, we recommend that the Department submits an updated SPA that reflects proposed rates using cost data that does not include "reasonableness" adjustments or adopts the current interim dispensing fee rates on a permanent basis. If neither of these solutions can be accomplished in a timely manner to avoid reversion to the pre-Pandemic rates, we ask that the State request an extension of the interim rate until a new SPA can be developed and implemented that reflects the actual cost of dispensing.

Department Response -

Thank you for your comment. As discussed, the interim rates were based on the 2019 survey which contained anomalies in the data underlying these rates. This necessitated the 2024 dispensing fee survey conducted by the Department to ensure the dispensing fees were based on accurate data. The difference between the interim and proposed rates is not reflective of artificial or arbitrary reductions. Rather it is the use of updated data collected through a survey that the Department engaged in actively with the Tribal Health Organizations. The interim dispensing fee is not based on, and does not reflect, the same quality of data.

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The Department has reviewed the request to remove the reasonable limits and does not believe the removal of that limit aligns with the Department's understanding and interpretation of federal regulations.

We have reached out to CMS regarding an extension of the interim dispensing fee and have confirmed no additional extensions will be approved.

Tribal Comment #2 - ANHB

As the Department is aware, section 1902(a)(30)(A) of the Social Security Act, commonly referred to as the "equal access provision," is a federal law intended to "assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." This provision requires states to pay providers enough to ensure that care and services are available on the same basis for beneficiaries for as the general population in the area.

<u>Department Response –</u>

Thank you for your comment. Our proposed fee structure, with projected higher Tribal rates than the rates established in 2014, is designed to maintain or even enhance access to care. Tribal Health Organizations have consistently provided comprehensive care under the established rates, and we expect the new structure to further support their efforts. Further, pharmacies have the ability to bill an additional fee when the dispensing pharmacy ships a prescription to a recipient and pharmacy services are not available in the recipient's community. In addition, pharmacists are able to bill as professional providers at the encounter rate for certain services. We believe the combination of these options meets the intent outlined above.

Tribal Comment #3 - ANHB

This provision also justifies setting appropriate dispensing fees based on actual cost-based data from Tribal pharmacies. Otherwise, the dispensing fees may not be consistent with this section. We also note that the regulatory definition of "professional dispensing fee" at 42 CFR § 447.502 includes those costs "associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient" whether or not directly related to patient care.

<u>Department Response</u> –

The Department is confident the proposed rates are compliant with the provisions of 42 CFR § 447.502, as well as 42 CFR § 447.518(d), section 1902(a)(30)(A) of the Social Security Act, CMS-2345-FC, and the guidance found in CMS Pub. 15-1, Section 2100.

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Under 42 CFR 447.502 the professional dispense fee includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.

Tribal Comment #4 - ANHB

The Department's imposition of a 5% "reasonableness" cap on indirect cost data means that the data used to develop the proposed rates does not reflect the true cost of dispensing as reported by Tribal pharmacies. These pharmacies serve enormous geographic areas that are extremely isolated. As just one example, the Tanana Chiefs Conference (TCC) pharmacy serves a geographic area over 235,000 square miles and stocks medications for 28 rural clinics throughout Interior Alaska. By providing high-quality, timely, and safe medication access close to the location of patients, saving millions of dollars in medical transports, morbidity and mortality are saved by the overall healthcare system at large. Oversight, regulatory compliance, quality improvement, security, billing/ financial, patient safety, controlled substance management, and a vast array of related services are delivered by Tribal pharmacies at hundreds of sites across the entire state on a daily basis.

Department Response -

All direct costs reported in the dispensing fee survey are included without limit in the dispensing fee rates. Myers and Stauffer recommended implementing a cap methodology to care for anomalies which have emerged among reported indirect costs. This methodology would cap a pharmacy's allowable indirect costs at 5% of the reported revenue of the parent organization. This approach, set at the median indirect cost percentage observed in all Tribal pharmacies controls for outliers and provides a data-driven approach to determining fees across diverse and small datasets inherent in Alaska's pharmacy landscape. The use of the median as a reasonableness limit on indirect costs is grounded, in that it represents the midpoint of all Tribal organizations and is not reflective of a bias toward urban or rural, high volume or low organizations.

The independent analysis of Tribal data apart from the general pool helps improve data uniformity among non-Tribal samples but results in a very small and variable subset of Tribal data. This creates challenges in managing outlier impacts, as smaller, more heterogeneous datasets are more susceptible to distortion by extreme values. Using the median, rather than the mean, to determine central tendency reduces the influence of these outliers and provides a balanced view of the costs. It represents an objective point, and further ties back to our attempt to represent the central tendency of cost data.

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<u>Tribal Comment #5 – ANHB</u>

In addition, Tribal pharmacies spend tremendous sums of money on expediting medications to patients in rural Alaska to treat both chronic and acute medical conditions. Tribal pharmacies employ tele pharmacy services to improve the quality, safety, and timeliness of care for patients in rural Alaska. And the Alaska Tribal Health System relies on pharmacists to improve health outcomes of AN/AI patients. Tribal pharmacies serve a vast array of clinical needs including outpatient, inpatient, emergency room, urgent care, Community Health Clinics, oncology and infusion centers, outpatient surgery centers, immunization services, and direct pharmacist-delivered primary care. To be clear, a majority of the cost saving, improving outcomes and safety-oriented patient care provided by Tribal pharmacists is not rendered in standard, billable clinical pharmacists-rendered visits.

Department Response -

Thank you for the services that you provide. CMS has repeatedly defined the costs allowable as part of the determination of the Professional Dispense Fee. Services such as "direct pharmacist-delivered primary care" are not part of this cost structure. Rather, they would be cared for through billing for pharmacist professional services. More details can be found in the Alaska Medicaid billing manuals and fee schedules.

Tribal Comment #6 - ANHB

These unique circumstances justify the continued Tribal-specific pharmacy dispensing fee. However, combined with the nature of the integrated organizational structures used by Alaska THOs, they also mean that the line between "direct" and "indirect" costs is not always perfectly clear. But that is irrelevant to the cost of dispensing—both "direct" and "indirect" costs are "associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient (42 CFR § 447.502)."

Department Response -

For the vast majority of the Tribal organizations, the overhead allocations and/or indirect cost reported appeared to be reasonable and accounted for a small percentage of the total expenses attributed to the cost of dispensing. However, for a small number of organizations, the amount of indirectly attributed or allocated expenses was high when compared to either directly reported expenses and/or overall revenue/sales of the facility. Outreach to these organizations yielded additional information and helped to refine the results. The outreach did not entirely resolve concerns that all indirectly reported expenses were both reasonable and related to patient care.

Tribal Comment #7 - ANHB

Previous discussion and communication with the Department suggests that the 5% reasonableness

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cap imposed on the data used to develop the proposed rates was intended to manage outliers and "anomalous indirect pharmacy cost data." Although we stand behind the veracity of the indirect costs that we have reviewed from Tribal pharmacies in their COD survey responses, we acknowledge DOH's concerns regarding how the CMS might view "outliers" in the COD survey data. However, capping indirect costs at the median reported value from Tribal pharmacies is an arbitrary and unjustifiable solution to this problem.

Department Response -

Thank you for your response, please see our response in Tribal comment #4.

Tribal Comment #8 - ANHB

To use a straightforward example, nothing in the COD survey responses or DOH's discussion of this matter suggests that a Tribal pharmacy that reported a 6% indirect cost, for example, is in any way anomalous or an outlier—but the Department would have nonetheless thrown out that reported data as an unreasonable outlier. Specifically, by setting a "reasonableness" cap, the Department made a determination that any reported indirect costs above that cap was inherently not "reasonable." And because the Department set the cap at the median, the result is that the reported indirect cost data from one-half of Tribal pharmacies was discarded for purposes of setting the pharmacy dispensing fee.

<u>Department Response – </u>

In the process of evaluating the surveys received from responding pharmacies, Myers and Stauffer conducted repeated outreach to clarify submissions which contained costs which lacked sufficient detail or clarity to be attributed to the cost of dispensing a prescription. In some cases, however, as a result of the accounting practices of the respondent, sufficient clarity was not possible. Inclusion of these costs as reported was not possible, as it would not only compromise the validity of any rates resulting from this cost pool, but it would also directly jeopardize the potential for approval of these rates by CMS. As a result, the Department worked closely with Myers and Stauffer to develop a solution to care for these reported costs without simply excluding them all as unsubstantiated. The reasonableness limit, as described in the survey report, was discussed with stakeholders in a series of meetings and ultimately adopted by the Department as the best available solution.

Tribal Comment #9 - ANHB

To the extent that the Department is required to make any adjustments to the reported cost data to satisfy concerns from CMS regarding outliers, the Department should use an established statistical method of identifying outliers. For example, the standard median-based statistical method for identifying outliers in a data set is to multiply the interquartile range by 1.5 and add that value to the third quartile. Setting the reasonableness cap at this point would result in a more equitable

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calculation that is no less objective or data-based than the flawed approach of setting the reasonableness cap at the median—and would be far easier to justify with CMS because it (unlike the approach used in developing the SPA rates) is based on a standard statistical method for identifying outliers.

Department Response -

While there are many different potential approaches to care for anomalous data, the Department worked closely with Myers and Stauffer and carefully considered the recommendation of their subject matter experts in the development of this solution. We remain confident and Myers and Stauffer believe it is the approach that is most reasonable and likely to receive federal approval it represents the best path forward and meets all CMS requirements.

Tribal Comment #10 - ANHB

Maintaining patient access to medications is critical to safeguarding public health. Tribal pharmacies are the de facto pharmacies for vast areas in the State of Alaska that are roadless and/or where health care is difficult to access. If pharmacy dispensing fees are not sufficiently reimbursed, health care providers have no alternative but to compensate for these costs in other areas of operating health programs, which in effect limits services and reduces access to health care for Medicaid beneficiaries. We strongly urge the Department to submit proposed dispensing fees that reflect the cost of dispensing without arbitrary "adjustments" or maintains the current interim rates on a permanent basis. And if the Department cannot do so in a manner avoids the threat of a disastrous reversion to pre-Pandemic rates, the Department should propose to extend the interim rates until a solution can be reached.

Department Response -

We appreciate the work Tribal pharmacies conduct in the state. While we understand the concerns with the new dispensing fees, the state needs to move forward with a rate that is based on the current cost of dispensing survey and must move forward with permanent rates.

<u>Tribal Comment #11 – Alaska Native Tribal Health Consortium (ANTHC)</u>

Before providing our comments and recommendations, we want to take this opportunity to acknowledge the Department for its work on the 2024 pharmacy dispensing survey. The State and Tribal efforts to conduct and respond to the survey and complete the analysis have taken a significant amount of personnel time and resources. We want the Department to know we appreciate its work to address the pharmacy dispensing issues in Medicaid. ANTHC has also been party to the development of the Alaska Native Health Board's (ANHB) comment and recommendations letter on this issue. ANTHC fully supports the discussion and recommendations that are included in the ANHB letter.

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Department Response -

Thank you for your continued work and collaboration with the Department, and your partnership with other Tribal Health Organizations.

Tribal Comment #12 - ANTHC

During the virtual Tribal consultation session held on April 29th, ANTHC explained our concerns about the Myers & Stauffer analysis of the 2024 Cost of Dispensing (COD) Survey and the rates that are included in the proposed SPA. We do not believe that the proposed rates accurately reflect the cost of dispensing fees in the State of Alaska. ANTHC discussed how the Department's imposition of a 5% "reasonableness" cap on indirect cost data means that the data used to develop the proposed rates does not accurately reflect the true cost of dispensing as reported by Alaska Tribal Health System (ATHS) pharmacies. We are also concerned about the timing to approve the SPA and implement a regulatory package by an effective date of July 1, 2025. During the consultation we discussed that the Medicaid dispensing fees must not revert back to the 2019 pre-COVID rates and all efforts should be made to prevent this scenario from happening.

Department Response -

We appreciate your concerns regarding state plan and regulatory alignment. The Department is pursuing the SPA in order to ensure federal financial participation, and we are working internally to ensure a July 1, 2025 effective date.

<u>Tribal Comment #13 –ANTHC</u>

In a number of meetings leading up to the Tribal consultation, ATHS partners have shared with the Department how we provide high-quality, timely, and safe medication access close to the location of patients, saving millions of dollars in medical transport, morbidity and mortality are saved by the overall healthcare system at large. Oversight, regulatory compliance, quality improvement, security, billing/ financial, patient safety, controlled substance management, and a vast array of related services are delivered by ATHS pharmacies at hundreds of sites across the entire state on a daily basis. In addition, ATHS pharmacies spend tremendous amounts of money on expediting medications to patients in rural Alaska to treat both chronic and acute medical conditions. Alaskan THO Pharmacies employ tele-pharmacy services to improve the quality, safety, and timeliness of care for patients in rural Alaska. And the ATHS relies on pharmacists to improve the health outcomes of AN/AI patients. Alaska's Tribal Health Pharmacies serve a vast array of clinical needs including outpatient, inpatient, emergency room, urgent care, Community Health Clinics, oncology and infusion centers, outpatient surgery centers, immunization services, and direct pharmacist-delivered primary care.

Department Response -

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We appreciate you highlighting the work pharmacies do in Alaska and appreciate your continued care of all Alaskans.

Tribal Comment #14 (1 - 4) - ANTHC

ANTHC Recommendations:

1. ANTHC applauds the State for the development of a distinct Tribal Health Pharmacy dispensing fee to appropriately reimburse Tribal pharmacies for their unique costs and reflect the health disparities of the population we serve. ANTHC recommends that the State continue to support and include this separate Tribal dispensing fee in the proposed SPA.

Department Response -

Thank you for your comment. We appreciate your continued support and participation in the survey to better represent the cost of dispensing in Alaska.

2. We further recommend that the Department submits an updated SPA that reflects proposed rates using cost data that does not include "reasonableness" adjustments; or adopt the current interim dispensing fee rates on a permanent basis.

Department Response -

While we appreciate the concerns regarding "reasonableness" limits, we are unable to adopt interim rates on a permanent basis and must move forward with updated fees.

3. If CMS indicates that the SPA will not be approved before the termination date for the interim rate, we recommend that the State request an extension of the interim rate until the SPA is approved.

Department Response -

We appreciate, and share, this concern. In the unlikely event that CMS cannot move this proposed SPA towards approval, we will work with our federal and Tribal partners in next steps. However, our intent is to submit the SPA well before the "file by" date to ensure ample review time for CMS to ensure a July 1, 2025 effective date.

4. Lastly, once a permanent SPA is adopted following the 2024 Cost of Dispensing (COD) Survey process, we urge the Department to begin planning for the next pharmacy dispensing survey to be conducted in the next two to three years. A part of the challenge related to the quality of the dispensing fee data is directly attributed to the survey instrument and how and the differences between how retail pharmacies are organized than Tribal pharmacies.

Department Response -

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We appreciate your willingness to participate in another cost of dispensing survey and we support conducting the survey on a more frequent basis. We appreciate your continued efforts to inform the Department of the role of Tribal pharmacies in the system of Alaska healthcare.

Tribal Comment #15 – Southcentral Foundation (SCF)

As previously communicated to DOH throughout the analysis of the 2024 Cost of Dispensing (COD) survey, and development of this SPA, the rates proposed in the SPA may not reflect the actual COD and will likely have significant negative impacts on the availability of services at Tribal pharmacies.

Department Response -

As we communicated in the FAQ¹ published by the Department, we believe that this survey more acutely reflects the cost of dispensing than previous surveys, and are eager to move forward with permanent, data-supported rates.

Tribal Comment # 16 - SCF

Southcentral Foundation (SCF) subject matter experts agree that any procedural delays in implementing a new SPA and associated regulatory package that would result in reverting to the prepandemic dispensing fee rate should be avoided. Additionally, the updated dispensing fee should be set using an objective, data-driven approach. However, the methodology used to establish this new proposed rate may fall short of that desired approach. To that end, the recommendation is that DOH submit an updated SPA that reflects proposed rates using cost data that does not include what has been deemed a "reasonableness" adjustment for indirect costs. Alternatively, DOH could pursue adoption of the current interim dispensing fee rates on a permanent basis. If neither of these solutions can be accomplished in a timely manner, the state should request an extension of the interim rate until a new SPA can be developed and implemented that reflects a more accurate cost of dispensing.

Department Response -

Please refer to Tribal Comment #4. We appreciate and agree with your desire to avoid reverting back to the pre-pandemic rate. CMS has expressed that we are unable to adopt the interim rates as permanent rates, and that we are not able to extend the disaster-related State Plan Amendment (dSPA) that allowed for the interim rate past the current expiration date.

Tribal Comment # 17 – SCF

DOH's use of a 5% "reasonableness" cap on indirect cost data means the data used to develop the proposed rates does not reflect the true cost of dispensing as reported by Tribal pharmacies. Tribal pharmacies serve enormous geographic areas that are often extremely isolated. Oversight, regulatory

¹ https://extranet-sp.dhss.alaska.gov/hcs/medicaidalaska/Provider/Updates/Pharmacy_Dispensing_FAQ_03282025.pdf

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compliance, quality improvement, security, billing/ financial, patient safety, controlled substance management, and related services are delivered by Tribal pharmacies at hundreds of sites across the state every day. Tribal pharmacies serve a diversity of clinical needs including outpatient, inpatient, emergency room, urgent care, community health clinics, oncology and infusion centers, outpatient surgery centers, immunization services, and direct pharmacist-delivered primary care.

Department Response -

Please refer to Tribal comment #4 for response.

Tribal Comment #18 - SCF

These unique circumstances justify the continued Tribal-specific pharmacy dispensing fee. Previous discussion and communication with DOH suggest that the 5% "reasonableness" cap imposed on the statewide data used to develop the proposed rates was intended to manage outliers and "anomalous indirect pharmacy cost data." However, capping indirect costs at the median reported value from Tribal pharmacies seems arbitrary.

Department Response -

Please refer to Tribal Comment #4.

Tribal Comment #19 - SCF

Nothing in the COD survey responses or DOH's discussion of this matter suggests that a Tribal pharmacy that reported a 6% indirect cost, for example, is anomalous or an outlier. However, the methodology being used in this proposal would exclude that reported data as an unreasonable outlier. Specifically, by setting a "reasonableness" cap, DOH seems to have decided that any reported indirect costs above that amount were inherently not "reasonable." And because the cap is at the median, the result is that the reported indirect cost data from half of the Tribal pharmacies were discarded for purposes of setting the pharmacy dispensing fee.

<u>Department Response – </u>

Please refer to Tribal comment #8 for response.

Tribal Comment #20 - SCF

To the extent that DOH is required to make any adjustments to the reported cost data to satisfy concerns from CMS regarding outliers, the Department should consider using an established statistical method for identifying outliers. Setting the reasonableness cap in this manner could result in a more equitable calculation that would be easier to justify to CMS because it is based on a standard statistical method for identifying outliers.

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<u>Department Response – </u>

Please refer to Tribal comment #9 for response.

<u>Tribal Comment #21 – Tanana Chiefs Conference (TCC)</u>

Through the Alaska Native Health Board, we have communicated to the Department of Health (Department) throughout the analysis of the 2024 Cost of Dispensing (COD) Survey and development of this SPA, the rates proposed in the SPA do not reflect the cost of dispensing and will have significant negative impacts on the availability of services at Tribal pharmacies including TCC's Chief Andrew Isaac Health Center Pharmacy (Fairbanks) and Upper Tanana Health Center Pharmacy (Tok).

Department Response -

Thank you for the services that you provide to all Alaskans throughout the state and those that are part of the Tribal health system. Please see Tribal comment #10 for further response.

Tribal Comment #22 - TCC

We recommend that the Department submits an updated SPA that reflects proposed rates using cost data that does not include "reasonableness" adjustments or adopts the current interim dispensing fee rates on a permanent basis. If neither of these solutions can be accomplished in a timely manner to avoid reversion to the pre-Pandemic rates, we ask that the State request an extension of the interim rate until a new SPA can be developed and implemented that reflects the actual cost of dispensing.

<u>Department Response – </u>

Please see responses to Tribal comments #1 and #4.

Tribal Comment #23 - TCC

The Department's imposition of a 5% "reasonableness" cap on indirect cost data means that the data used to develop the proposed rates does not reflect the true cost of dispensing as reported by Tribal pharmacies.

Department Response -

Please refer to responses to Tribal comment #4.

Tribal comment #24 - TCC

These unique circumstances justify the continued Tribal-specific pharmacy dispensing fee. However, combined with the nature of the integrated organizational structures used by Alaska THOs, they also

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mean that the line between "direct" and "indirect" costs is not always perfectly clear. But that is irrelevant to the cost of dispensing-both "direct" and "indirect" costs are "associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient."

Department Response -

Please refer to Tribal comment #3.

Tribal Comment #25 - TCC

Specifically, by setting a "reasonableness" cap, the Department made a determination that any reported indirect costs above that cap was inherently not "reasonable." And because the Department set the cap at the median, the result is that the reported indirect cost data from one-half of Tribal pharmacies was discarded for purposes of setting the pharmacy dispensing fee. To the extent that the Department is required to make any adjustments to the reported cost data to satisfy concerns from CMS regarding outliers, the Department should use an established statistical method of identifying outliers. For example, the standard median-based statistical method for identifying outliers in a data set is to multiply the interquartile range by 1.5 and add that value to the third quartile. Setting the reasonableness cap at this point would result in a more equitable calculation that is no less objective or data-based than the flawed approach of setting the reasonableness cap at the median-and would be far easier to justify with CMS because it (unlike the approach used in developing the SPA rates) is based on a standard statistical method for identifying outliers.

Department Response -

Please see response to Tribal comment #9.

Tribal Comment # 26 – TCC

We strongly urge the Department to submit proposed dispensing fees that reflect the cost of dispensing without arbitrary "adjustments" or maintains the current interim rates on a permanent basis. And if the Department cannot do so in a manner avoids the threat of a disastrous reversion to pre-Pandemic rates, the Department should propose to extend the interim rates until a solution can be reached.

Department Response -

Please see response to Tribal comment #14.

Sincerely,

Christal Hays

Christal Hays, Medicaid State Plan Coordinator