

# Annual Evaluation: Impact on CMS and ACA-Related Actions from Tribal Involvement in the Regulatory Process

FY 2015 Report

(October 1, 2014 - September 30, 2015)

October 27, 2015

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# I. Purpose of Report

Regulations and other guidance documents issued by the Centers for Medicare and Medicaid Services (CMS)<sup>1</sup> and other federal agencies pertaining to Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Patient Protection and Affordable Care Act (ACA) have a direct effect on the Indian health care system.

The purpose of this report (Report) is to evaluate the impact of tribal involvement in the federal regulatory process.

# II. Evaluation of Tribal and Federal Agency Actions

This Report summarizes the activities conducted by Tribes and tribal organizations, including NIHB<sup>2</sup> and the Tribal Technical Advisory Group to CMS (TTAG),<sup>3</sup> during the federal regulatory process. The Report also identifies which tribal recommendations were acted upon by federal agencies – either by being implemented as requested or by explaining why a recommendation was not accepted – as well as which recommendations remain to be acted upon.

More specifically, the evaluation presented in this Report will –

- Quantify the level of (formal) participation of Tribes and tribal organizations in the federal regulatory process.
- Assess whether this participation contributes to the understanding by CMS and other federal agencies of how agency actions might affect financing and delivery of health care services in the Indian health care system and access to health care services by American Indians and Alaska Natives (AI/ANs).
- Evaluate the extent to which tribal involvement in the regulatory process has had an impact on the regulations and other guidance documents issued by CMS (and

<sup>&</sup>lt;sup>1</sup> CMS is an agency of the federal Department of Health and Human Services (HHS).

<sup>&</sup>lt;sup>2</sup> Established over 40 years ago, NIHB is an inter-Tribal organization that advocates on behalf of Tribal governments for the provision of quality health care to all Al/ANs. NIHB is governed by a Board of Directors consisting of a representative from each of the twelve Indian Health Service ("IHS") Areas. Each Area Health Board elects a representative to sit on the NIHB Board of Directors. In areas where there is no Area Health Board, Tribal governments choose a representative who communicates policy information and concerns of the Tribes in that area with NIHB. Whether Tribes operate their entire health care program through contracts or compacts with IHS under Public Law 93-638, the Indian Self-Determination and Education Assistance Act ("ISDEAA"), or continue to also rely on IHS for delivery of some, or even most, of their health care, NIHB is their advocate.

<sup>&</sup>lt;sup>3</sup> TTAG advises CMS on Indian health policy issues involving Medicare, Medicaid, CHIP, and any other health care program 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 Al/ANs under these federal health care programs, including through providers operating under the health programs of IHS, Tribes, tribal organizations, and urban Indian organizations (I/T/Us).

- related agencies) pertaining to ACA implementation, as well as operation of the Medicare, Medicaid, and CHIP programs.
- Identify issues of concern and tribal recommendations that have not been acted on by agencies and, as such, remain outstanding.
- Identify responses by agencies to tribal recommendations that indicate a
  potential willingness to address the recommendation in the future.

The Report covers the federal regulatory activities, and the corresponding tribal involvement in the regulatory process, over the period of October 1, 2014 – September 30, 2015 (FY 2015).

A limitation to this analysis is that the evaluation begins with the formal regulatory action taken by the federal agency and assesses the extent to which subsequent agency actions are responsive to tribal concerns. In many instances, tribal representatives interacted with agency officials prior to the initial regulatory action. In some cases, tribal concerns were addressed in the initial regulatory action. In these instances, the responsiveness of CMS and other federal regulatory agencies to tribal requests occurred prior to the formal regulatory process. As such, this evaluation does not capture the impact of tribal representatives on the pre-formal regulatory process actions.

# III. NIHB Regulatory Review Process

Through the support of a cooperative agreement with CMS, over the past two years NIHB monitored regulations proposed by CMS and other federal agencies in the implementation of the ACA and the management of the Medicaid, CHIP, and Medicare programs. NIHB identified regulatory proposals that might have the greatest impact on AI/ANs and the health programs of I/T/Us.

NIHB catalogued the recommendations made by Tribes and tribal organizations in response to the proposed federal rules. Then, NIHB monitored and evaluated subsequent actions of federal agencies to determine the extent to which the recommendations of Tribes and tribal organizations were adopted by CMS and other federal agencies.

In conducting the review of federal regulatory actions over the past quarter, NIHB undertook the following key tasks, often on a daily basis:

Review the Federal Register and HHS and other federal agency Web sites
regularly to identify CMS and ACA-related regulations and guidance documents
issued that might affect I/T/U providers and AI/AN access to health care services.

- Identify the regulatory actions with the greatest potential or actual impact on AI/AN access to health care services under Medicare, Medicaid, CHIP, and coverage offered through an Exchange.
- Prepare and submit to CMS and Tribes and tribal organizations a monthly report (the Regulation Review & Impact Analysis Report, or RRIAR) that captures the regulations that were identified and evaluated.
- Between the releases of the monthly reports, prepare a roster of pending federal regulations (Roster), on a near-daily basis, to provide an at-a-glance status report on proposed regulations with pending due dates for comments.

In addition to these actions, NIHB produces these quarterly reports that summarize the degree of tribal involvement in the federal regulatory process and the extent of CMS responsiveness to tribal recommendations.

# IV. Tribal Involvement in the Federal Regulatory Process

Based on the tracking effort outlined above, TTAG, NIHB, the Tribal Self-Governance Advisory Committee to IHS (TSGAC), as well as individual Tribes, Area Health Boards and other tribal organizations, when warranted, prepared comments in response to CMS and other ACA-related proposed regulations and guidance.

In particular, the Roster aided Tribes and tribal organizations in:

- Prioritizing pending regulatory actions in regard to which ones are most relevant to Al/ANs and I/T/Us and
- Determining whether formal comments would be prepared and submitted by tribal organizations.

Copies of the RRIAR and the Roster appear on the NIHB Tribal Health Resource Web site at <a href="http://www.nihb.org/tribalhealthreform/rriar/">http://www.nihb.org/tribalhealthreform/rriar/</a>. Comments submitted by TTAG, NIHB, and others in response to proposed regulations are available on the NIHB Tribal Health Resource Web site at <a href="http://www.nihb.org/tribalhealthreform/ttag-regulation-comments">http://www.nihb.org/tribalhealthreform/ttag-regulation-comments</a>.

# Proposed Regulations Tracked over October 1, 2014 – September 30, 2015

Over the last year (Fiscal Year 2015, or FY 2015), NIHB tracked approximately 293 CMS-related and ACA-related proposed regulations and other guidance documents that were proposed or acted upon by CMS and other federal agencies during this period. Each of these pending actions was included in versions of the Roster, and each proposed or final action is captured in the monthly RRIAR, which cumulates activities

over a calendar year. For instance, the RRIAR dated December 31, 2014, captures all regulatory actions tracked since January 1, 2014. In the near-daily Roster, a summary of each agency action (proposed or final) was provided, and tribal representatives and technical advisors reviewed the Roster weekly to identify priority regulatory actions.

Of the 293 regulatory actions tracked this fiscal year, TTAG, NIHB, and/or other tribal entities *filed comments on 22 of these*, or roughly 8 percent of the total. The regulatory actions on which tribal organizations filed comments are shown in **Attachment 1 (page 16)**. Each regulatory action is designated by the associated RRIAR reference number.

Aside from filing comments to influence the content of the finalized regulations, the review of proposed (and final) regulations enables Tribes and tribal organizations, for themselves and on behalf of Al/ANs and I/T/Us, to understand the various Medicaid, Exchange, and other program regulations within which they are to operate.

In Table 1 below, a breakdown is provided of the proposed regulations or other guidance documents issued by federal agencies on which tribal organizations filed comments. The agency actions are listed by activity type (i.e., regulation, Paperwork Reduction Act (PRA) notice, or guidance/other notices) and by issuing agency (i.e., CMS, other HHS agencies, the Internal Revenue Service (IRS)/Treasury Department, the Office of Personnel Management (OPM), and the Department of Veterans Affairs (VA). CMS includes the sub-agencies CCIIO (Center for Consumer Information and Insurance Oversight) and CMCS (Center for Medicaid and CHIP Services.)

Table 1. Tracking Number of Agency Notices on Which Tribal Entities Filed Comments

	CMS (CCIIO and CMCS)	Other HHS	IRS/Treasury	ОРМ	VA	Total
Regulations	6	2	0	0	1	9
PRA Requests	1	0	0	0	0	1
Guidance/Other	6	1	4	0	1	12
Total Notices	13	3	4	0	2	22

As shown in Table 1, the majority of the comments by tribal organizations (13 of 22, or 59 percent) were focused on regulatory actions of CMS and its component agencies. The remaining 9 comments were focused on the regulatory actions of other HHS agencies (3), IRS/Treasury (4), and VA (2).

# V. Federal Agency Actions and Responsiveness to Tribal Recommendations

The primary goal in Tribes and tribal organizations filing comments with federal agencies in response to proposed rules is to –

• Educate federal agencies on the need and value of modifying the proposed rule to better address concerns of Al/ANs, Tribes, and tribal organizations to compel the federal agencies to modify the regulation prior to publishing a final version.

Success in achieving this goal can be measured by assessing the extent to which agency proposed rules were modified in the final rule.

Related, but secondary, goals in filing comments are to –

- Ensure federal agencies are aware of potential downsides to the proposed actions even if there might not be a good remedy or the negative result might not be avoidable.
- Educate federal agencies on issues of concern to Al/ANs and I/T/Us for which future actions might be taken by those agencies.

Whether these goals were achieved can be measured, in part, by determining if a) the agency acknowledged the tribal comment and indicated whether a remedy is available or not, b) the agency took action on the tribal recommendation, and/or c) the agency indicated it might take or consider action in the future on the issue.

<u>Final Regulations Issued by Federal Agencies and Tracked in RRIAR over October 1,</u> 2014 – September 30, 2015

Of the regulatory actions tracked by NIHB over FY 2015, 35 regulations (or other forms of guidance documents) were finalized and published by CMS and/or other federal agencies.

These final actions are listed in **Attachment 2 (page 18)**. Each final action is designated by the associated RRIAR reference number.

Of the final regulatory actions taken by CMS or other federal agencies in FY 2015, TTAG, NIHB, and/or other tribal organizations previously *filed comments on 9 of the 35 regulatory proposals* (the final regulations issued in which tribal organizations submitted formal comments are shown in bold in **Attachment 2**).

# **Evaluation of Federal Agency Actions**

NIHB conducted an analysis of each subsequent agency action to determine the extent to which agencies responded to comments filed by tribal organizations, if any, expressing tribal concerns and/or recommendations. In a typical comment letter that is submitted in response to a proposed rule, tribal organizations offer multiple recommendations. The NIHB evaluation is documented in the monthly RRIARs.

In Table 2, there is a tracking of all FY 2015 actions, which include recommendations made by tribal organizations in FY 2015 and agency actions taken in FY 2015 on current and prior recommendations. A breakdown is provided of the agency responses in FY 2015 to the individual recommendations by tribal organizations, by agency and by response type. A total of 123 individual tribal recommendations were made in FY 2015. A total of 53 individual tribal recommendations are contained in rules or other guidance documents for which the agency issued a final or subsequent version in FY 2015.

Table 2. Individual Recommendations by Tribal Entities Made or Acted on by Agencies in FY 2015

	CMS (CCIIO and CMCS)	Other HHS (e.g., HRSA)	IRS/ Treasury	OPM	VA	Total	
Tribal Recommendations Made in FY 2015							
Recommendations on Rules Subsequently Acted on by Agencies in FY2015	30	0	8	0	0	38	
Recommendations on Rules Not Subsequently Acted on by Agencies in FY 2015	58	12	9	0	6	85	
TOTAL	88	12	17	0	6	123	
Current and Prior Tribal Recommendations Contained in Rules Acted on by Agencies in FY 2015							
Addressed Issue as Recommended	8	0	6	2	0	16	
Acknowledged Issue by Other Means	10	0	0	0	0	10	
Did Not Address Issue	23	0	4	0	0	27	
TOTAL	41	0	10	2	0	53	

Of the 123 tribal recommendations made in FY 2015, 38 were subsequently acted on by agencies in FY 2015. The remaining 85 tribal recommendations made in FY 2015 addressed proposed rules or other guidance documents for which the agency did not issue a final or subsequent version in FY 2015.

For the 53 individual (current or prior) tribal recommendations that were contained in rules or other guidance documents for which the agency issued a final or subsequent version in FY 2015, the type of response taken by the agency is noted in the second half of Table 2. The response types "Addressed Issue as Recommended" and "Acknowledged Issue by Other Means" are both considered positive responses.

Of the 53 total recommendations made by tribal organizations for which a subsequent regulation has been issued in FY 2015, a majority (41) was directed to CMS, which addressed issue as recommended for 8 of them. "Addressed Issue as Recommended" indicates the agency response met the primary goal of compelling the agency to take the recommended action. This was generally achieved by modifying the regulation itself to adopt the recommendation or providing a clarification in the preamble to the final rule. Among other agencies, IRS/Treasury and OPM adopted some of the recommendations made by tribal organizations, accepting 6 and 2 of them, respectively.

The second response type ("Acknowledged Issue by Other Means") also is considered a favorable response, although to a lesser extent. Typically, the agency acknowledged the issue raised and either 1) stated its rationale for not adopting the recommendation or 2) indicated that it will consider acting on the recommendation in future regulations or guidance documents. The recommendations that fall in this category are considered to have received a somewhat positive response because the agency response indicates, at a minimum, that it is aware of the potential downsides to a proposed action even if it believes the tribal recommendation might not be an available or workable remedy. Or, more favorably, the tribal comments educated the federal agency on an issue of concern to Al/ANs and I/T/Us for which the agency indicates a future action might be taken.

Under "Did Not Address Issue," no response or favorable acknowledgement to the tribal recommendation could be found in the subsequent agency action.

## Responsiveness of Federal Agencies

In Table 3 below, a "responsiveness quotient" – the percentage of the recommendations of tribal organizations on which agencies acted favorably – is presented, shown by agency grouping.

Fewer than half (.44) of the recommendations associated with regulations that have been finalized by CMS are shown as "responsive." (This includes 18 recommendations – 8 adopted and 10 acknowledged – out of 41 recommendations contained in regulations that had a subsequent regulatory action taken.)

It is important to note that the .44 score does not represent the proportion of the tribal recommendations that were adopted. The adoption rate is much lower, at .20 (8 out of 41) for CMS-related recommendations. Other federal agencies had a responsiveness rate of .67 and an adoption rate of .67.

	CMS (CCIIO and CMCS)	Other Agencies	All Agencies
Responsiveness Quotient*	.44	.67	.49
Adoption Quotient**	.20	.67	.30

Table 3. Agency Responsiveness to Recommendations by Tribal Entities

The responsiveness quotient indicates the degree to which the agency considered and formulated a response to the tribal recommendations.

# Prioritizing Tribal Recommendations and Agency Responses

It also is important to note that not all recommendations have equal importance. Some of the recommendations made by tribal organizations were of secondary (or lesser) importance when compared with other recommendations. Given the complexity in doing so, the responsiveness quotient was not adjusted to factor in the relative importance of various recommendations.

# VI. Status of Tribal Recommendations Made Through the Regulatory Process

A final component of this evaluation is to identify which issues and recommendations made by tribal organizations through the regulatory process remain outstanding.

Tribal Recommendations Outstanding Due to Regulations Not Yet Finalized

<sup>\*</sup>Calculated by dividing the number of recommendations of Tribal entities on which an agency acted favorably (through adoption or acknowledgement by other means) by the total number of tribal recommendations acted upon by the agency.

<sup>\*</sup>Calculated by dividing the number of recommendations of Tribal entities adopted by an agency by the total number of tribal recommendations acted upon by the agency.

Of the 160 individual recommendations with some type of activity in FY 2015 (i.e., tribal organizations made recommendations or an agency acted on prior tribal recommendations), 107 remain outstanding due to the associated regulation not yet being finalized. In **Attachment 3 (page 21)**, a list of pending (i.e., pre-final) regulations for which tribal recommendations were made in FY 2015 is shown (Section A), as well as a list of pending regulations for which recommendations were made in the previous fiscal year (Section B). Greater detail on each item in Section A may be found in the 2015 RRIAR (v. 5.09) by using the included RRIAR reference number, and greater detail on each item in Section B may be found in the 2015 RRIAR (v. 5.09), 2014 RRIAR (v. 4.12), 2013 RRIAR (v. 3.12), or 2012 RRIAR (v. 2.12).

#### Tribal Recommendations Not Fully Addressed in Agency Responses in FY 2015

In **Attachment 4 (page 59)**, a status is indicated for each of the tribal recommendations acted on by federal agencies through the regulatory process in FY 2015. Greater detail on each item may be found in the 2015 RRIAR (v. 5.09) or 2014 RRIAR (v. 4.12) by using the included RRIAR reference number. For some recommendations, there are multiple RRIAR reference codes if the recommendation or issue was raised in more than one regulation.

**Attachment 4** provides a "yes" or "no" answer to whether the agency 1) "Addressed Issue as Recommended" or 2) "Acknowledged Issue and/or Addressed by Other Means."

In the final column in **Attachment 4**, a summary statement is provided on the current status of each recommendation. It is hoped that, by reviewing this column, tribal organizations, as well as CMS and other federal agencies, will be able to identify priority items to direct future efforts.

Information on the status of tribal recommendations acted on by federal agencies prior to FY 2015 is available in **Attachment 4** in the past evaluation reports for FY 2014 and FY 2013.

# Potential Opportunity to Advance Tribal Recommendations Initially Not Accepted

In response to several tribal recommendations, federal agencies indicated a willingness to reconsider the issue in the future.

In **Attachment 5 (page 90)**, Section A, there is 1 recommendation on which the agency, in its response in FY 2015, indicated the potential for future action (in some form). This involved a proposal by CMS to open for one month the Essential Community Providers Provider Petition for the 2017 Benefit Year (Petition) for providers to make corrections and updates to their entries on the HHS ECP List. Among other

issues with this proposal, tribal organizations raised concerns that the one-month window might not allow sufficient time for the hundreds of non-IHS Indian health care providers (ICHPs) to access and update their information through the Petition. In its response, CMS stated that it will consider a request from tribal organizations for a grace period or a transition year prior to removing otherwise qualified providers from the HHS ECP List.

**Attachment 5,** Section B includes past tribal recommendations on which agencies indicated in prior reporting periods the potential for future action.

In setting an agenda for future tribal priorities, Tribes and tribal organizations might want to focus on the items listed in **Attachment 5**, as well as revisit some of the recommendations that were not initially accepted in full, were rejected, or were ignored.

Details for some of the recommendations Tribes and tribal organization might wish to continue to pursue appear in **Attachment 4 (page 59)**. A comprehensive review of **Attachment 4** by tribal representatives is warranted to ensure limited resources are directed to the recommendations that remain the highest priorities with the greatest chance of agency acceptance and implementation.

# Agency Action/Inaction in FY 2015 on Past Tribal Recommendations with Potential for Future Action

Among past tribal recommendations on which federal agencies indicated the potential for future action, agencies had the opportunity to act, but declined to act, on a number of recommendations in FY 2015 and did act on 1 of them.

First, CMS did not act on a recommendation made on the draft 2015 Letter to Issuers in Federally-Facilitated Marketplaces (FFMs). In FY 2014, tribal organizations recommended that CMS require issuers to make available plans allowing three primary care office visits before a patient must meet any deductible.

CMS did not discuss this issue in the final letter. However, CMS stated, generally: "Some policies with operational implications in the Draft 2015 Letter to Issuers are not being finalized in this Final 2015 Letter to Issuers, with the intent to continue work to accomplish them." On December 19, 2014, CMS promulgated the draft 2016 Letter to Issuers in FFMs. Neither this draft letter nor any regulations issued subsequent to the initial tribal recommendation has addressed this issue.

Second, CMS did not act on a recommendation made on the HHS Notice of Benefit and Payment Parameters for 2014 (CMS-9964-P). In comments submitted in FY 2013, tribal organizations recommended that CMS, for families with AI/AN and non-AI/AN members, should:

- Calculate the aggregate family premium by calculating the premium for each family member when enrolled in a single family policy at the silver metal level;
- Enroll the family members in two separate plans that may be different in only the family type and the cost-sharing variation, with no change in the aggregate premium paid; and
- Establish the maximum out-of-pocket liability for the "non-Al/AN plan" as a proportion of the maximum liability of a single family plan.

In its initial response, CMS did not address this issue but indicated it would reconsider it in future years. In FY 2014, CMS declined to address this issue in the HHS Notice of Benefit and Payment Parameters for 2015 (CMS-9954-F). On November 26, 2014, CMS released the proposed HHS Notice of Benefit and Payment Parameters for 2016 (CMS-9944-P), which again did not address this issue. Tribal organizations reiterated their concerns about this issue in comments submitted to CMS on December 22, 2014. In CMS-9944-F, CMS did not address this issue.

CMS did, however, act on a recommendation made on Modifications to the EHR Incentive Programs for 2014 (CMS-0052-P), which addressed Stage 2 of these programs. In comments submitted in FY 2014, tribal organizations recommended that CMS not require providers to implement Stage 3 until 2018 to allow the necessary time to adapt to the new requirements. CMS did not address this issue in its initial response but stated that it would consider concerns about Stage 3 after the release of a subsequent proposed rule regarding this stage. On March 30, 2015, CMS issued Electronic Health Record Incentive Program—Stage 3 (CMS-3310-P). This proposed rule would make implementation of Stage 3 optional in 2017 and mandatory in 2018.

Among other federal agencies, OPM in FY 2015 had the opportunity to act, but declined to act, on a series of past tribal recommendations related to the Multi-State Plan Program for Exchanges. A list of these recommendations appears in **Attachment 5** (page 90).

#### Attachments

- Attachment 1: Regulatory Actions Tracked in RRIAR in FY 2015 on Which Tribal Organizations Filed Comments (page 17)
- Attachment 2: Final Regulations Issued by Federal Agencies and Tracked in RRIAR over October 1, 2014 – September 30, 2015 (page 18)
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# Attachment 1: Regulatory Actions Tracked in RRIAR in FY 2015 on Which Tribal Organizations Filed Comments

Each action is designated by the associated RRIAR reference number.

- 1. 64.b. CMS Tribal Consultation Policy (CMS/no ref. #; comments submitted 10/1/2014)
- 2. 31.bb. Health Coverage Exemptions (Form 8965; comments submitted 10/30/2014)
- 3. 185.d. Revisions to Safe Harbors Under the Anti-Kickback Statute, et al. (OIG-403-P3; comments submitted 12/2/2014 by TTAG)
- 4. 89.h. Notice of Benefit and Payment Parameters for 2016 (CMS-9944-P; comments submitted 12/22/2014 by TTAG)
- 5. 70.d. Revisions to PFS and Other Changes to Part B for CY 2015 (CMS-1612-FC; comments submitted 12/23/2014)
- 6. 7.vv. 2016 Letter to Issuers in FFMs (CCIIO/no ref. #; comments submitted 1/12/2015 by TTAG)
- 7. 92.ll. Health Benefit Plan Network Access and Adequacy Model Act (NAIC/no ref. #; comments submitted 1/12/2015 by TTAG)
- 8. 112.e. Tribal Consultation on VA/IHS Reimbursement Agreements (VA/no ref. #; comments submitted 1/14/2015 by TSGAC)
- 112.d. I/T/U Payment for Physician and Non-Hospital-Based Services (IHS/RIN 0917-AA12; comments submitted 2/4/2015)
- 10. 31.pp. Summary of Benefits and Coverage and Uniform Glossary (REG-145878-14, DoL/RIN 1210-AB69, CMS-9938-P; comments submitted 2/28/2015 by TTAG)
- 11. 41.e. New Safe Harbors (OIG-123-N; comments submitted 3/2/2015 by TTAG)
- 12. 112.c. Expanded Access to Non-VA Care Through Veterans Choice (VA/RIN 2900-AP24; comments submitted 3/5/2015)
- 13. 64.c. Tribal Consultation Policy (Treasury/no ref. #; comments submitted 4/2/2015)
- 14. 31.ss. Excise Tax on High Cost Employer Health Coverage (Notice 2015-16; comments submitted 5/15/2015)
- 15. 1.I. EHR Incentive Program—Stage 3 (CMS-3310-P; comments submitted 5/29/2015)

- 16. 89.k. Eligibility Determinations for Indian-Specific CSVs (TTAG/no ref. #)1
- 17. 7.ccc. Out-of-Pocket Cost Comparison Tool for FFMs (comments submitted 6/29/2015 by TTAG)
- 18. 154.b. Medicaid/CHIP Managed Care (CMS-2390-P; comments submitted 7/27/2015)
- 7.ddd. ECP Data Collection to Support QHP Certification for PY 2017 (CMS-10571; comments submitted 8/4/2015)
- 20. 70.e. Revisions to PFS and Other Changes to Part B for CY 2016 (CMS-1631-P; comments submitted 9/8/2015 by TTAG)
- 21. 31.aaa. Excise Tax on High Cost Employer Health Coverage (Notice 2015-52; comments submitted 9/30/2015)
- 22. 89.I. Referrals for Cost-Sharing Protections Under Limited CSVs (CMS/no ref. #; comments submitted 9/30/2015)

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<sup>&</sup>lt;sup>1</sup> TTAG submitted this letter to CCIIO in response to potential problems with Marketplace eligibility determinations for Indian-specific cost-sharing protections and other related issues. This letter provides recommendations for addressing these concerns but does not respond to a specific regulation or guidance document.

# Attachment 2: Final Regulations Issued by Federal Agencies and Tracked in RRIAR over October 1, 2014 – September 30, 2015

The final regulations issued on which tribal organizations submitted formal comments are shown in bold.

Each final action is designated by the associated RRIAR reference number.

- 1. 31.t. Amendments to Excepted Benefits (TD 9697, DoL/RIN 1210-AB60, CMS-9946-F; issued 10/1/2014)
- 2. 174.c. FEHBP: Eligibility for Temporary and Seasonal Employees (OPM/ RIN 3206-AM86; issued 10/17/2014)
- 3. 52.m. Home Health PPS Rate Update for CY 2015, et al. (CMS-1611-F; issued 11/6/2014)
- 4. 71.m. Medicare ESRD PPS, Quality Incentive Program, and DMEPOS (CMS-1614-F; issued 11/6/2014)
- Hospital OPPS and ASC Payment System, et al. (CMS-1613-FC; issued 5. 4.k. 11/10/2014)
- 6. 70.d. Revisions to PFS and Other Changes to Part B for CY 2015 (CMS-1612-FC; issued 11/13/2014)
- 7. 29.n. Premium Tax Credit (Form 8962; issued 11/13/2014)
- 8. 31.bb. Health Coverage Exemptions (Form 8965; issued 11/13/2014)
- 9. 31.x. MEC and Other Rules on the Shared Responsibility Payment (TD 9705; issued 11/26/2014)
- 10. 46.a. Medicaid DSH and Definition of Uninsured (CMS-2315-F; issued 12/3/2014)
- 11. 121.b. Medicare Incentive Reward Program and Provider Enrollment (CMS-6045-F; issued 12/5/2014)
- 12. 174.e. FEHBP Miscellaneous Changes: Medically Underserved Areas (OPM/no ref. #; issued 12/17/2014)
- Beneficiary and Family Centered Care QIO Contract Evaluation (CMS-3296-FN; 13. 13.i. issued 12/30/2014)
- 14. 13.i. Evaluation Criteria for QI Program Contracts (CMS-3300-FN; issued 12/30/2014)
- 15. 66.c. Additional Requirements for Charitable Hospitals (TD 9708; issued 12/31/2014)
- 16. 31.mm. 2016 Actuarial Value Calculator (CCIIO/no ref. #; issued 1/16/2015)

- 17. 11.gg. CY 2016 Policy and Technical Changes to Parts C and D (CMS-4159-F2; issued 2/12/2015)
- 18. 7.vv. 2016 Letter to Issuers in FFMs (CCIIO/no ref. #; issued 2/20/2015)
- 19. 39.e. Basic Health Program: Federal Funding Methodology for 2016 (CMS-2391-FN; issued 2/20/2015)
- 20. 111.e. Establishment of Multi-State Plan Program for Exchanges (OPM/RIN 3206-AN12; issued 2/24/2015)
- 21. 145.d. Health Insurance Providers Fee (TD 9711; issued 2/26/2015)
- 22. 89.h. Notice of Benefit and Payment Parameters for 2016 (CMS-9944-F; issued 2/27/2015)
- 23. 157.c. Right of Appeal for Medicare Secondary Payer Determination (CMS-6055-F; issued 2/27/2015)
- 24. 31.oo. Amendments to Excepted Benefits (TD 9714, DoL/RIN 1210-AB70, CMS-9946-F2; issued 3/18/2015)
- Medicare and Medicaid Survey, Certification, and Enforcement (CMS-3255-F; issued 5/22/2015)
- 26. 10.c. Medicare Shared Savings Program: ACOs (CMS-1461-F; issued 6/9/2015)
- 27. 174.f. FEHBP: Rate Setting for Community-Rated Plans (OPM/RIN 3206-AN00; issued 6/10/2015)
- 28. 31.pp. Summary of Benefits and Coverage and Uniform Glossary (TD 9764, DoL/RIN 1210-AB69, CMS-9938-F; issued 6/16/2015)
- 29. 31.dd. Coverage of Certain Preventive Services Under ACA (TD 9726, DoL/RIN 1210-AB67, CMS-9940-F; issued 7/14/2015)
- 30. 72.e. PPS and Consolidated Billing for SNFs for FY 2016, et al. (CMS-1622-F; issued 8/4/2015)
- 31. 25.x. Medicare PPS for Inpatient Psychiatric Facilities for FY 2016 (CMS-1627-F; issued 8/5/2015)
- 32. 25.y. Medicare PPS for Inpatient Rehab Facilities for FY 2016 (CMS-1624-F; issued 8/6/2015)
- 33. 25.z. PPS for Acute and Long-Term Care Hospitals for FY 2016, et al. (CMS-1632-F; issued 8/6/2015)
- 34. 78.i. Hospice Rate Update for FY 2016 (CMS-1629-F; issued 8/6/2015)

35. 64.c. Tribal Consultation Policy (Treasury/no ref. #; issued 9/3/2015)

# Attachment 3: Pending Regulations on Which Tribal Organizations Filed Comments

These are pending regulations or guidance on which tribal organizations have filed comments, with each item designated by the associated RRIAR reference number. Beneath each item appears a list of related recommendations made by tribal organizations. Section A includes recommendations that tribal organizations made in FY 2015, and Section B includes recommendations that tribal organizations made previously.

#### A. Recommendations Made in FY 2015

1. 64.b. CMS Tribal Consultation Policy (CMS/no ref. #; comments submitted 10/1/2014)

## NIHB recommendations

- a. New Regulations and CMS Centers—Notable changes in federal Indian policy and regulations—through the American Recovery and Reinvestment Act (ARRA), ACA, and Section 1115 Waiver Transparency regulations—have occurred since CMS developed the tribal consultation policy (TCP); CMS should adopt these key policy changes into the TCP, as well as integrate two new CMS centers—CCIIO and the Center for Medicare and Medicaid Innovation (CMMI).
- **b. TTAG Assistance**—CMS should re-engage the TTAG Tribal Consultation Subcommittee to assist CMS in review of the comments received from this tribal and state consultative process.
- c. Tribal Requests for Consultation—CMS should re-engage the TTAG Tribal Consultation Subcommittee to assist CMS in review of the comments received from this tribal and state consultative process.
- d. CMS Obligations—CMS should include in the TCP reference to its obligations regarding providing direction to states and their responsibility to conduct consultation with tribal health providers.
- e. Mandatory Consultation—The TCP makes consultation with Tribal organizations permissive, instead of mandatory, even though tribal organizations have received authority to carry out programs for the Tribe under the ISDEAA; CMS should make consultation mandatory.
- f. Time Frames for Consultation—CMS should include in the TPC time frames for initiating the consultation process and specify how this consultation should occur.
- g. Meeting Records Availability—The TCP requires CMS to make readily available all TTAG meeting records and recommendations; CMS should include in the TCP a requirement that it post this information.

- h. Reference to HHS TCP—The CMS TCP relies on a reference to the HHS TCP rather than restating the language, requiring readers to have both in hand to fully appreciate the significance of tribal sovereignty; CMS should add this language in its TCP.
- **i. Definitions**—CMS should address in the TCP the following issues regarding definitions:
  - **Consultation**: The TCP does not include TTAG among the parties in the consultation;
  - Critical Events: The TCP limits these events to those arising within CMS, excluding other components of HHS;
  - Indian: The TCP does not reference the definitions in 42 C.F.R. § 447.50 for the purposes of CMS programs or ACA;
  - **Indian Tribe**: The TCP does not include reference to other entities included in definition of "Indian Tribe" under IHCIA;
  - **Indian Health Provider**: The TCP excludes the phrase "Indian health provider" and does not define this term;
  - Joint Tribal/Federal Workgroups and/or Task Forces; Native American: The TCP does not include these terms; and
  - To the Extent Practicable and Permitted by Law: The TCP does not include the clarification, as recommended by TTAG, that "permitted by law" should include anything not expressly prohibited by law.
- **j. Enforcement Mechanism**—CMS should develop an enforcement mechanism to ensure states meet their obligations to consult with Tribes on their Medicaid programs and consult with TTAG about what specific state obligations require enforcement.
- **k. Section 1115 Waiver Applications and ARRA**—CMS should work with TTAG on the issues of waiver applications submitted under the Section 1115 Waiver Transparency regulations and mechanisms to solicit advice and input from Tribes under ARRA and address these concerns in the TCP with specific language with regard to how states consult with Tribes, including a definition of the consultative process and a feedback mechanism for CMS to verify that states have officially followed this process.
- 2. 185.d. Revisions to Safe Harbors Under the Anti-Kickback Statute, et al. (OIG-403-P3; comments submitted 12/2/2014 by TTAG)

# TTAG recommendations

- **a. Local Transportation Services Safe Harbor**—The proposed rule would establish a new safe harbor that would protect free or discounted local transportation to assist patients in obtaining medically necessary items and services, with possible limitations for transportation exceeding 25 miles and for beneficiaries visiting a facility at which they are not an "established patient"; in regard to this proposed safe harbor, HHS OIG should:
  - Not implement the 25-mile limit, which would essentially disqualify many I/T/Us and AI/AN patients located in isolated areas, and implement instead its alternative proposal to authorize transportation under the safe harbor to "the nearest facility capable of providing medically necessary items and services";
  - Explicitly recognize that, in the case of IHS beneficiaries, the safe harbor should extend to non-emergency transportation to the nearest capable I/T/U facility, even when a closer non-I/T/U facility exists; and
  - Not implement the "established patient" limit, which would serve as a barrier between AI/AN patients and access to care.
- **b.** Access to Care Promotion Safe Harbor—The proposed rule would establish a safe harbor to exempt any "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs" from the list of prohibited kickbacks; HHS OIG should retain this safe harbor, which could help encourage AI/ANs to make and keep primary care appointments and engage in preventive services, and should consult with TTAG and Indian health providers in developing standards that will protect Federal health care programs while still encouraging access to primary and preventive care.
- **c. Safe Harbors for Pharmacy and Emergency Ambulance Cost-Sharing Reductions**—The proposed rule would establish two safe harbors authorizing providers to waive patient cost-sharing 1) for pharmacies (including those operated by an I/T/U) that waive Medicare Part D cost-sharing and 2) for emergency ambulance services for ambulance suppliers owned and operated by a State, political subdivision of a State, or a federally-recognized Tribe, with a possible extension to cost-sharing under Medicaid and other Federal health care programs; in regard to these safe harbors, HHS OIG should address the following issues:
  - Emergency Ambulance: To avoid excluding tribal organizations authorized by federally-recognized Tribes to carry out health programs on their behalf, HHS OIG should extend this safe harbor to these groups by amending references to ambulance services "owned and operated by a State or political subdivision of a State" to read as either:
    - "Owned and operated by a State or political subdivision of a State, or a federally recognized Indian tribe, or a tribal organization as that term is

- defined in Section 4 of the Indian Health Care Improvement Act [25 U.S.C. § 1603]"; or
- "Owned and operated by a State or political subdivision of a State, or tribal health program, as that term is defined in Section 4 of the Indian Health Care Improvement Act [25 U.S.C. § 1603]."
- **Extension to Medicaid**: HHS OIG should extend these safe harbors to Medicaid and other Federal health care programs.
- Application of Cost Sharing: To avoid an argument that Tribal health programs would violate the anti-kickback statute if they (rightfully) waive cost-sharing for Al/ANs in contexts outside the scope of these safe harbors, HHS OIG should include the following clause: "Nothing in this provision shall require any facility operated by the Indian Health Service, an Indian tribe, a tribal organization, or an urban Indian organization to collect any cost-sharing amount from any individual eligible to receive services from the Indian Health Service as a condition of satisfying Section 1128B(b) of the Act."
- d. Prohibitions on Advertising for Safe Harbor Services—Several of the proposed safe harbors include the condition that they "not [be] advertised or part of a solicitation"; HHS OIG should remove these prohibitions on advertising or solicitation, as they eliminate potentially the only opportunity for I/T/Us to inform the target patient population of an option through which they can afford primary and preventive care, or at a minimum, include some version of the following: "For the purposes of this provision, 'advertisements' and 'solicitations' does not include information provided to a patient in person from a provider, a notice of patient rights on a facility website discussion of charity care, the rights of Indian Health Service beneficiaries, or similar opportunities to waive or reduce patient responsibilities, or any information transmitted directly to a patient as part of a reminder of upcoming appointments or a statement of benefits and coverage."
- 3. 70.d. Revisions to PFS and Other Changes to Part B for CY 2015 (CMS-1612-FC; comments submitted 12/23/2014)

#### NIHB recommendations

a. Exemption from Penalties for IHS Providers—The current design of both incentives and penalties under the meaningful use (MU) policy does not take into consideration the many complexities and challenges for IHS providers, and a lack of adequate time and ability to deploy serves as a real barrier to achieving MU; CMS should exempt IHS providers from penalties for non-compliance with MU or, at a minimum, change the policy from 356 days attestation to 90 days attestation in 2015.

- **b.** Investment for Assisting IHS Providers to Achieve MU—IHS providers received a small and inadequate initial investment for assisting them to achieve MU, especially when considering the lack of resources, both in technology and technical assistance, in the system; CMS should conduct a formal review of the level of federal funding needed to address the rapidly emerging digital divide imposed upon tribal health systems and to sustain a level playing field for I/T/Us to thrive in a reformed health care delivery environment.
- 4. 92.II. Health Benefit Plan Network Access and Adequacy Model Act (NAIC/no ref. #; comments submitted 1/12/2015 by TTAG)

#### TTAG recommendations

- a. Inclusion of Indian Health Providers (IHPs) in Networks—The most geographically accessible and culturally appropriate primary care providers often work in clinics and hospitals operated by IHS, Tribes, and tribal organizations, and although it would make sense for health carriers to include IHPs in their networks, barriers to this practice exist; to reduce these barriers, NAIC should:
  - Include in the Model Act a section specific to IHPs that the 34 states with federally-recognized Tribes could adopt and other states could choose to omit; and/or
  - Amend the language throughout the Model Act to accommodate the distinctive characteristics of IHPs.
- **b. Definition of Essential Community Provider (ECP)**—The Model Act does not include a definition of ECP, although one exists; NAIC should add the following language:

"Essential community provider" means a provider that serves predominantly low income, medically underserved individuals, including a provider defined in Section 340B(a)(4) of the PHSA and a tax exempt entity that meets the requirements of that standard except that it does not receive funding under that section.

- **c. Definition of Health Care Professional**—The Model Act defines a health care professional as "a physician or other health care practitioner licensed, accredited or certified to perform specified health services *consistent with state law*" (emphasis added); the phrase "consistent with state law" might prove problematic for IHPs because federal law allows professionals licensed in a different state to practice in IHS and tribal facilities, and as such, NAIC should revise this definition.
- **d. Definition of IHP**—The Model Act includes no definitions related to Indian health care; NAIC should add the following definition of IHP:

A facility or program that is funded in part by the federal government or a federally-recognized Tribe to serve primarily American Indians and Alaska Natives, including the federal Indian Health Service, facilities and programs that are operated by Tribes and Tribal Organizations, and urban Indian clinics (also called "I/T/U").

- e. Geographic Accessibility—Section 5, Part A of the Model Act creates the standard of network adequacy with regard to types of providers, and Part B allows health carriers to use any of eight reasonable criteria, which include (3) Geographic accessibility and (4) Geographic population dispersion; the concept of geographic population dispersion might prove contradictory, providing an exception to geographic accessibility, and as such, NAIC should seek to ensure that, if IHPs (or other types of providers) already operate in remote areas or areas with low population density, health carriers offer networks that include these providers.
- **f. Obtaining Covered Benefits from Out-of-Network Providers**—Section 5, Part C of the Model Act addresses the two cases in which health carriers must allow covered individuals to obtain covered benefits from out-of-network providers; NAIC should add a third case to specify that Al/ANs can access services from geographically accessible IHPs, a provision that already exists in current law and Medicaid and qualified health plan (QHP) regulations.
- g. Access Plans—The Model Act requires health carriers to submit access plans that describe or contain 11 items; NAIC should add to item (2), "The health carrier's procedures for making and authorizing referrals within and outside its network, if applicable," details about how plans in states with IHPs will coordinate with Indian health facilities for referrals, as well as add an additional item that requires carriers in states with federally-recognized Tribes to document their good faith efforts to include IHPs in their networks.
- **h. Anti-Discrimination Provisions**—Section 6, F(3) of the Model Act includes provisions to prevent discrimination against providers in the establishment of health carrier networks; to prevent discrimination against IHPs, NAIC should include, either in a special Indian health section or in the section related to anti-discrimination, a requirement that carriers make a good faith effort to offer provider contracts to all IHPs.
- 5. 112.e. Tribal Consultation on VA/IHS Reimbursement Agreements (VA/no ref. #; comments submitted 1/14/2015 by TSGAC)

#### TSGAC recommendations

**a. Direct Communication with Tribal Health Programs**—VA should establish communication with tribal and urban health programs regarding all aspects of its

implementation of the Veterans Access, Choice and Accountability Act of 2014 and other department initiatives, as IHS cannot speak for these programs.

- **b. Inclusion of Tribal Health Programs in New Agreement Negotiations**—To the extent that VA considers new model language or agreements to streamline contracting with I/T/Us to provide services to AI/ANs, in addition to IHS representatives, any negotiations or discussions should include tribal and urban health program representatives to ensure recognition of the differences between IHS and tribal and urban health programs.
- c. Inclusion of Tribal Health Programs in Development of Performance Metrics—
  Tribal and urban Indian health program representatives should serve as participants in satisfying the requirement of section 102(b) of identifying and developing the performance metrics for both VA and IHS under their Memorandum of Understanding regarding increasing access to health care, improving quality and coordination of health care, promoting effective patient-centered collaboration and partnerships between VA and IHS, and ensuring funding and availability of health-promotion and disease-prevention services for beneficiaries under both health care systems.
- **d. Recommendation for Entering and Expanding Agreements with I/T/Us**—In its report to Congress, VA should recommend entering agreements with I/T/Us for reimbursement of the costs of services provided to eligible non-AI/AN veterans and, when possible, using and expanding these agreements to accelerate the implementation of all aspects of the efforts by VA to expand access to health care to eligible veterans.
- 6. 112.d. I/T/U Payment for Physician and Non-Hospital-Based Services (IHS/RIN 0917-AA12; comments submitted 2/4/2015)

#### NIHB recommendations

- a. Treatment of Professional Services Under Existing Medicare-Like Rate Regulations—The titles for Subpart I and Section 136.201 erroneously suggest that current Medicare-Like Rate regulations do not apply to care provided by physicians and other health care professionals; IHS should clarify that the rule applies to all non-hospital providers (including non-hospital based physicians and other health care professionals).
- **b. Section 136.201(a)(1)(3)**—Section 136.201 states that I/T/Us can pay only the lowest of either (1) the Medicare-Like Rate; (2) a rate negotiated by the I/T/U or its repricing agent; or (3) the amount the provider "bills the general public for the same service," but (3) seems vague and might result in misinterpretation; IHS should change this provision to the amount the provider "accepts as payment for the same service from nongovernmental entities, including insurance providers."
- **c. Need for Exceptions in New Section 136.201(b)**—Section 136.201(a) cites Medicare-Like Rates as the highest rates IHS could pay, and this lack of discretion

renders this provision unworkable in many areas in Indian country; IHS should allow I/T/Us the discretion and flexibility to deal with unique circumstances that might necessitate negotiating a rate different from, or even higher than, the Medicare-Like Rate by adding the following sections to the rule:

- Section 136.201(b)(1): This section, which would apply to Tribes and tribal
  organizations that have negotiated agreements with IHS under the Indian SelfDetermination and Education Act and urban Indian organizations, would make
  clear that they have the right to choose not to apply the rule; and
- **Section 136.201(b) (2)**: This section would allow I/T/Us, when necessary, to negotiate a rate with providers higher than the rate provided for in Section 136.201(a), capping the rate at no more than what the provider charges non-governmental entities, including insurance providers, for the same service.
- **d. Tribal Consultation**—The proposed rule would have significant tribal implications and substantial direct effects on one or more Tribes; IHS should engage in tribal consultation before finalizing the rule.

# 7. 41.e. New Safe Harbors (OIG-123-N; comments submitted 3/2/2015 by TTAG)

#### TTAG recommendations

- a. Safe Harbor for Waiver of Beneficiary Coinsurance and Deductibles—HHS OIG should extend to Al/ANs eligible for IHS services the current safe harbor for a reduction or waiver of the obligation of a Medicare or State health care program beneficiary to pay coinsurance or deductibles.
- **b. Review of Summary of Benefits and Coverage (SBC) Template**—HHS OIG should create the following safe harbors:
  - A safe harbor specific to I/T/U providers, modeled after the existing safe harbor authorizing Federally Qualified Health Centers "to accept certain remuneration that would otherwise implicate the anti-kickback statute when the remuneration furthers a core purpose of the Federal health centers program: ensuring the availability and quality of safety net health care services to otherwise underserved populations";
  - A safe harbor authorizing exchanges or transfers of value among and between IHCPs;
  - A safe harbor authorizing IHCPs to share other resources, including practitioner services and facility space, among one another; and

- A safe harbor authorizing IHCPs to offer free or reduced-cost goods or services to IHS-eligible individuals to encourage healthy lifestyle choices and the use of preventive care, improve public safety, facilitate keeping health care appointments, etc.
- 8. 112.c. Expanded Access to Non-VA Care Through Veterans Choice (VA/RIN 2900-AP24; comments submitted 3/5/2015)

#### NIHB recommendations

- **a. Use of Existing Agreements**—In the Preamble to the Interim Final Rule, VA states that it will "to the maximum extent practicable and consistent with the requirements of section 101, use existing sharing agreements, existing contracts, and other processes available at VA medical facilities prior to using provider agreements" under section 101; VA should follow through with this comment and use existing sharing agreements with I/T/U facilities to implement section 101, rather than requiring these facilities to negotiate new agreements.
- **b. Inclusion of Tribes in Consultation**—Although IHS plays an important role in the funding and support of tribal and urban Indian health programs, the agency cannot speak for these programs; VA should include Tribes in any consultation on the implementation of the Interim Final Rule, as opportunities might exist for Tribes to offer services or programs that IHS cannot.
- 9. 31.ss. Excise Tax on High Cost Employer Health Coverage (Notice 2015-16; comments submitted 5/15/2015)

#### NIHB recommendations

- a. Exclusion of Tribal Employers from the Excise Tax Based on Longstanding Rules of Statutory Interpretation: Section 9001 of ACA, which established Internal Revenue Code (Code) section 4980I, applied the excise tax to excess benefits provided under "applicable employer-sponsored coverage," as defined in subsection 4980I(d)(I); this subsection, however, does not mention coverage administered by Tribes or tribal organizations, despite specifically addressing state governments and the federal government, and under longstanding rules of statutory interpretation, IRS should consider the decision by Congress to exclude these entities from Section 4980I as a deliberate action and, as such, should exclude tribal coverage from the excise tax.
- b. Exclusion of Tribal Employers from the Excise Tax Based on Policy Considerations: Congress has recognized the importance of maintaining and improving the health of Indians, as well as ensuring their access to health care services, as part of the federal Indian trust responsibility, but the application of the excise tax to

tribal employers that administer their own plans would undercut these goals by forcing tribal employers to 1) pay the tax and divert funding from necessary services, 2) replace existing coverage specifically designed to meet the needs of the tribal workforce with lower-cost and less appropriate coverage, or 3) eliminate coverage; these policy considerations support excluding tribal coverage from the excise tax, and IRS should acknowledge them in any future regulations on this issue.

- c. Exclusion of Coverage Provided to Tribal Member Employees from the Excise Tax Based on the Definition of "Applicable Employer-Sponsored Coverage": The term "applicable employer-sponsored coverage" under section 4980I means coverage "under any group health plan made available to the employee by an employer which is excludable from the employee's gross income under section 106" of the Code or "would be so excludable if it were employer-provided coverage (within the meaning of such section 106)"; coverage for Tribal member employees, however, is excluded from income pursuant to section 139D, not section 106, and, as such, does not fall under the definition of "applicable employer-sponsored coverage" in section 4980I, and IRS should clarify this distinction to ensure that the excise tax is not levied against coverage provided by a tribal employer to a tribal member employee, as well as consult with tribal organizations regarding application of the tax to Tribes.
- d. Exclusion of Certain Benefits from the Scope of the Excise Tax: IRS requested comments on whether it should exclude certain benefits—1) certain types of onsite medical coverage, 2) Employee Assistance Program (EAP) benefits, and 3) self-insured dental and vision coverage—from the scope of the excise tax; the agency should exclude all three of these benefits from the excise tax and should expand the exclusions to include services provided at the nearest appropriate tribal health program (whether or not on site) and services provided to any employee by an I/T/U program for workplace-related health issues.
- **e. Adoption of "Permissive Disaggregation" Rules**: In most cases, IRS will determine the value of coverage for the purposes of the excise tax by evaluating the average plan cost among all "similarly situated beneficiaries," and regarding this issue, the agency requested comments on whether it should issue "permissive disaggregation" rules under which employers could designate plan beneficiaries as "similarly situated" based on either a broad standard or a more specific standard; IRS should adopt broad permissive disaggregation rules that maximize employer flexibility to group plan beneficiaries according to the unique needs of its workforce.
- f. Adoption of a Past Cost Method for Calculating Plan Value: IRS requested comments on the manner in which self-insured plans would calculate plan values to compare against the statutory threshold, proposing three primary options—1) an actuarial method that would calculate the cost of coverage for a given determination period using "reasonable actuarial principles and practices," 2) a past cost method that would make the cost of coverage equal to the cost to the plan for similarly situated beneficiaries for the preceding determination period (adjusted for inflation), or 3) an

actual cost method that would make the cost of coverage equal to the actual costs paid by the plan to provide coverage for the preceding determination period; IRS should adopt some version of the past cost method, excluding overhead expenses from this calculation, and should consult with tribal organizations to address the specifics of this issue.

g. Application of "Good Faith Interpretation" in Implementation of "Controlled Group Rules": Section 4980I states that, for the purposes of calculating plan values, the "controlled group rules" imposed by ERISA apply; however, IRS has explicitly reserved application of the controlled group rules to governmental employers and has stated that governmental entities can "apply a reasonable, good faith interpretation" of the rules in other ACA-related contexts—such as the employer mandate—and, as such, the agency should recognize, either in future regulations or guidance, that the good faith interpretation of the controlled group rules by Tribes applies for the purposes of both the employer mandate and the excise tax and that satisfying the standard in one context will equally satisfy the standard in the other.

# 10. 1.l. EHR Incentive Program—Stage 3 (CMS-3310-P; comments submitted 5/29/2015)

## NIHB recommendations

- a. Regulations/Definitions Across the Medicare Fee-for-Service, Medicare Advantage, and Medicaid Programs:
  - Single Reporting Period Aligned to Calendar Year: The proposed rule would create a single electronic health record (EHR) reporting period aligned to the calendar year would help achieve a stated goal of Stage 3 to realign and simplify the reporting process; CMS should retain this provision in the final rule.
  - Specification of Means of Data Transmission: For Stage 3, the proposed rule would continue to allow states to specify the means of transmission of the data and otherwise change the public health agency reporting objective; in the final rule, CMS should grant IHS, tribal health clinics, urban Indian clinics (I/T/Us) the same allowance, given the difficulties with Internet access in Indian Country.
  - "Topping Out": The proposed rule would eliminate the need for providers to report individually on measures for which they have already met the meaningful use (MU) threshold ("topping out"), thereby lessening the reporting burden; CMS should retain this provision in the final rule but should take into consideration that I/T/Us might not "top out" on the most basic measures, calling for flexibility in the way the agency determines if a provider has met the MU threshold.
  - Paper-Based Formats: The proposed rule would not allow the continued use of paper-based formats for certain objectives and measures in Stage 3; CMS

- should exclude I/T/Us from the provision because of the lack of Internet access in Indian Country.
- HIPAA Security Rules: HIPAA Security Rules require covered entities and business associates to conduct a security risk analysis to assess the potential risks to the electronic protected health information (ePHI) they create, receive, maintain, or transmit, but most, if not all, I/T/Us cannot afford the run this analysis as needed to meet the MU requirements in the proposed rule; CMS should take this into consideration in the final rule.
- Electronic Prescribing (eRx): eRx serves as one of eight objectives for MU in 2017 and subsequent years, and the proposed rule would require eligible professionals (EPs) to generate and transmit permissible prescriptions electronically and eligible hospitals and critical access hospitals (CAHs) to generate and transmit permissible discharge prescriptions electronically requirements that I/T/U would have difficulty meeting because of the rural nature of Indian Country; CMS should exclude I/T/Us from these requirements in the final rule.
- Clinical Decision Support (CDS): CDS—which concerns positive impact on the quality, safety, and efficiency of care delivery—serves as another of the eight objectives for MU in 2017, but I/T/Us will have difficulty achieving MU if they must have computerized alerts and reminders for providers and patients, information displays or links, context-aware knowledge retrieval specifications, InfoButtons, clinical guidelines, condition-specific order sets, focused patient data reports and summaries, documentation templates, diagnostic support, and contextually relevant reference information as the proposed rule would require; CMS should exclude I/T/Us from these requirements in the final rule.
- Computerized Provider Order Entry (CPOE): I/T/Us also would have difficulty
  meeting the proposed objective regarding CPOE for Stage 3, as the proposed
  rule would require including diagnostic imaging—such as ultrasound, magnetic
  resonance, and computed tomography in addition to traditional radiology—not
  commonly found in Indian Country; CMS should exclude I/T/Us from these
  requirements in the final rule.
- Patient Electronic Access to Health Information: In addition, I/T/Us would have difficulty meeting the proposed objective that, as required by the proposed rule, allows patients to view, download, and transmit their health information to a third party and engage in patient-centered communication for care planning and care coordination, as well as have timely access to their full health record, as these providers (and their patients) lack the necessary tools; in the final rule, CMS should exclude I/T/Us and their patients from the "no paper allowed" doctrine for Stage 3 and reconsider requirements on application-program interfaces (APIs) for Indian Country.

- Patient Electronic Access to Health Information Exclusion: The proposed rule would exclude from this objective any clinic located in a county in which 50 percent or more of its housing units lack 4 Mbps broadband availability and in which a significant section of the patient population does not have access to broadband Internet; CMS should retain this exclusion in the final rule.
- Coordination of Care Through Patient Engagement: CMS should retain in the final rule an exclusion from this objective for any clinic located in a county in which 50 percent or more of its housing units lack 4 Mbps broadband availability and in which a significant section of the patient population does not have access to broadband Internet.
- Transitions of Care: This proposed objective seeks to ensure the electronic transmission or capture of a summary of care record and the incorporation of this record into the EHR for patients seeking care among different providers in the care continuum, as well as to encourage reconciliation of health information for the patient; the summary of care measure in this objective raises some concerns based on the current status of health information exchange and the ability to partner with other organizations at this time, and as such, CMS should consider a more practical approach that would allow for a demonstration of the capability of a facility and consider implementation of rates in the future.
- Public Health and Clinical Data Registry Reporting: This objective focuses on the importance of the ongoing lines of communication that should exist between providers and public health agencies (PHAs) or between providers and clinical data registries (CDRs); this objective raises concerns because of the proposed requirement on bidirectional immunization exchange, a functionality that will require unanticipated additional development for vendors in the current year, and as such, CMS should reconsider this requirement.

## b. Certified EHR Technology (CEHRT) Requirements:

- Consolidating Reporting: The proposed rule seeks to (1) avoid redundant or duplicative reporting and align certain aspects of the reporting clinical quality measures (CQMs) component of MU under the Medicare EHR Incentive Program and Physician Quality Reporting System (PQRS) for EPs and (2) avoid redundant or duplicative reporting of CQM reporting requirements for the Medicare and Medicaid EHR Incentive Program for eligible hospitals and CAHs in the inpatient prospective payment system (IPPS); CMS should retain these provisions in the final rule.
- Electronic Reporting of CQMs: For 2018 and subsequent years, the proposed rule would require providers participating in Medicare to report CQMs electronically, where feasible, and remove the option of attestation to CQMs, except in circumstances where electronic reporting is not feasible; for I/T/Us in

10/27/2015

Indian Country where electronic reporting is not feasible, CMS should allow an alternative process.

HITECH Act Exemption: The HITECH Act requires reductions in payments to EPs, eligible hospitals, and CAHs that do not meet MU requirements, but the HHS secretary has the authority to exempt an affected EP if this reduction would result in a significant hardship; CMS should grant I/T/Us in Indian Country a permanent exemption.

# 11. 89.k. Eligibility Determinations for Indian-Specific CSVs (TTAG/no ref. #)

#### TTAG recommendations

- a. Eligibility: CCIIO should—
  - Audit the eligibility determination algorithm used by the Federally-Facilitated Marketplace (FFM) to confirm implementation of the eligibility determinations for the two Indian-specific cost-sharing variations (CSVs) in the application computer program and the determination process according to federal regulations and discuss the findings with TTAG.
  - Indicate on the FFM determination letters the specific cost-sharing variation for which an Indian applicant has qualified (the "02" or "03" CSV) and provide a summary description of the relevant Indian-specific CSV.

#### b. General Protections: CCIIO should—

- Increase education of qualified health plan (QHP) issuers on Indian-specific costsharing protections by:
  - Providing language on the Indian-specific CSVs for inclusion in QHP Summary of Benefits and Coverage documents due by October 2015.
  - Requiring issuers to indicate on their insurance cards the type of CSV applicable to the enrollee.
- Communicate the availability of the Health Insurance Complaint System (HICS) and permit tribal sponsors of enrollees to submit multiple (repeat) cases involving a single QHP but multiple QHP enrollees in one HICS submission.
- Ensure QHP issuers apply the Indian-specific CSVs correctly, drawing upon filings through HICS to identify erroneous application of Indian-specific CSVs, and prioritize conducting broader audits of the application of Indian-specific CSVs.

# c. Payments to Indian Health Care Providers: CCIIO should—

- Ensure QHP issuers make full payments to Indian health care providers, without deducting waived cost-sharing amounts.
- Communicate availability of HICS and permit providers to submit multiple (repeat) cases involving a single QHP in one submission.
- **d. Shorthand Descriptions of Indian-Specific CSVs**: CCIIO should consider adopting one or more of the following abbreviated descriptions for use by CMS when it requires a shorthand version of the explanation of the Indian-specific CSV—

#### OPTION 1:

- 00 Non-Exchange variant
- 01 Exchange variant (no CSR)
- 02 Open to Indians between 100% and 300% FPL
- 03 Open to Indians of any income level, or income not determined
- 04 73% AV Level Silver Plan CSR
- 05 87% AV Level Silver Plan CSR
- 06 94% AV Level Silver Plan CSR"

# OPTION 2:

- "02" or "Zero cost-sharing variation" protections are available to persons who
  meet the ACA's definition of Indian, have household income between 100
  and 300 percent FPL, are eligible for premium tax credits, and enroll in
  coverage through a Marketplace.
- "03" or "Limited cost-sharing variation" protections are available to persons
  who meet the ACA's definition of Indian, have any household income level,
  and enroll in coverage through a Marketplace.
  - Persons eligible for the limited cost-sharing variation do not have to be eligible for premium tax credits and can decide to not request an eligibility determination for insurance affordability programs (e.g., premium tax credits).

#### OPTION 3:

o "Zero cost-sharing variation" ("02")

Protections available to persons enrolled in coverage through a Marketplace who:

- Meet the ACA's definition of Indian
- Have household income between 100 and 300 percent FPL
- Qualify for premium tax credits
- o "Limited cost-sharing variation" ("03")

Protections available to persons enrolled in coverage through a Marketplace who:

- Meet the ACA's definition of Indian
- Have household income of any level
- Do or do not qualify for premium tax credits

To receive the "02" or "03" protections, an individual cannot be enrolled in a family plan with individuals who are not eligible for the "02" or "03" protections.

# 12. 7.ccc. Out-of-Pocket Cost Comparison Tool for FFMs (comments submitted 6/29/2015 by TTAG)

## TTAG recommendations

- a. Eligibility for Indian-Specific Cost-Sharing Protections: Footnote 1 in the CMS Bulletin on the Proposed OOP Cost Comparison Tool (OOP CCT) includes an inaccurate description of the eligibility criteria for each of the two Indian-specific cost-sharing variations (CSVs); CCIIO should replace this description (both in this document and in all other documents that contain a similar description) with the corrected version below:
  - "Zero cost-sharing variation" protections are available to individuals who meet the ACA definition of Indian, have household income between 100 percent and 300 percent of the federal poverty level (FPL), qualify for premium tax credits, and enroll in coverage through the Marketplace.
  - "Limited cost-sharing variation" protections are available to individuals who meet the ACA definition of Indian, have household income of any level, and enroll in coverage through the Marketplace.
    - Individuals eligible for the limited cost-sharing variation do not have to qualify for premium tax credits and can decide not to request an eligibility determination for insurance affordability programs (e.g., premium tax credits).

- b. Applicability of CSVs in Silver-Level Plans: To ensure that the OOP CCT benefits individuals receiving one of the CSVs—either those available to the general population (sometimes referred to as the "04." "05." and "06" variant codes) or available to Indians (sometimes referred to as "02" or "03" variant codes)—CCIIO should incorporate into the tool the impact of these cost-sharing protections to the computations made and the consumer-focused information displayed; CCIIO also should add a fourth factor, "applicable cost-sharing variation," to the description of the "data inputs" for the tool.
- c. Applicability of Indian-Specific CSVs at All Metal Levels: Displaying the impact of the Indian-specific CSVs for each plan offered at each metal level will prove critical to helping an Indian applicant understand the impact of the available cost-sharing protections, and the absence of such information will present an inaccurate depiction of the Indian-specific CSVs, and of Marketplace enrollment generally; CCIIO should ensure that the OOP CCT displays the impact of the Indian-specific CSV for which an Indian applicant qualifies for plans at each metal level.
- d. Estimated Impact of Balance Billing: The CMS Bulletin includes no discussion of the potential impact of "balance billing," a practice under which out-of-network providers can charge patients more than the amounts agreed upon by the plan issuer and the providers, or of a related concern, the breadth of a plan provider network, although both of these factors will prove important to Indian applicants in comparing potential OOP costs under various plan options; to address these issues in the OOP CCT, CCIIO should:
  - Include a standard statement (with an illustrative example) that services received from out-of-network providers might result in charges beyond the amounts shown in the OOP CCT and that the narrower the offering of in-network providers, the greater the likelihood a plan enrollee might experience balance billing charges; or
  - Provide a specific estimate of balance billing charges experienced under Marketplace coverage and adjust these estimated charges by the breadth of the provider network included under each plan offered.
- e. Out-of-Network Provider Charges: Under "Health Plan Cost Sharing Design, i. Plan and Benefits Data," the CMS Bulletin states that the "inputs would be structured for all services that are consumed for Tier-1 in-network ... services," and as with balance billing charges, providing an indication of potential OOP costs arising from services received from out-of-network providers will prove important to an applicant making an informed plan choice; to enable OOP CCT users to tailor the information displayed, CCIIO should add an option that allows users to display "OOP for all in-network providers" or "OOP for in-network and out-of-network providers."
- f. Availability and Use of OOP CCT: CCIIO has designed the OOP CCT for use under the Federally-Facilitated Marketplace (FFM); CCIIO should make the OOP CCT available for adoption by State-Based Marketplaces (SBMs).

## 13. 154.b. Medicaid/CHIP Managed Care (CMS-2390-P; comments submitted 7/27/2015)

#### NIHB recommendations

- a. Clarification States Cannot Obtain a Waiver of § 1932(a)(2)(C): Although CMS has consistently rejected attempts by states to force AI/ANs into managed care through section 1115 waivers, the agency should codify this policy in the final rule, as Medicaid managed care entities (MCEs) lack experience or incentive to work with Indian health systems.
- b. Section 483.14(b)(1)—Network Adequacy: Proposed § 438.14(b)(1) would require MCEs to have "sufficient" IHCPs in their networks; in the final rule, CMS should amend this section to require that MCEs demonstrate sufficiency by 1) offering network provider agreements using an Indian Managed Care Addendum at the request of IHCPs in their service area; 2) allowing into their networks any IHCP that seeks to participate; and 3) waiving for IHCPs any limitation placed on the number of providers in their networks.
- c. Oversight of Managed Care Plans: To promote strong oversight of states and their managed care plans to ensure their compliance with the Indian-specific requirements in proposed § 438.14, CMS in the final rule should:
  - Cross-reference the quality assessment requirements in proposed section 438, Subpart E with § 438.14;
  - Require that managed care plans actively and regularly provide verification of compliance with the Indian-specific requirements;
  - Require states to hold their managed care plans accountable, with consequences for failing to meet the IHCP network adequacy and other Indianspecific requirements; and
  - Offer technical assistance by maintaining a current list of the IHCPs in managed care plan service areas to allow the plans to know who to contact about participating in their networks.
- d. Section 483.14(b)(5)—Access to Services in States with Few or No IHCPs: Proposed § 483.14(b)(5) provides that, in states where a guarantee of timely access to covered services cannot occur because of the presence of "few or no" IHCPs, CMS would consider MCEs in compliance with the network adequacy standards of § 483.14(b)(1) if Indian enrollees can access out-of-state IHCPs or the "circumstance is deemed to be good cause for disenrollment from both the [MCE] and the State's managed care program in accordance with section 438.56(c)"; in the final rule, CMS should remove the phrase "few or" from this section and, regarding good cause for disenrollment, add the stipulation that "there is a fee-for-service alternative."

- e. Sections 483.14(b) and 438.9(b)—Non-Emergency Transportation: States can contract with entities that provide only non-emergency medical transportation (NEMT), and although these prepaid ambulatory health plans (PAHPs)—referred to as NEMT-PAHPs—must meet the requirements identified in proposed § 438.9(b), the special provisions applicable to other MCE contracts involving Al/ANs, IHCPs, and Indian managed care entities (IMCEs) appear in § 438.14; CMS should amend the final rule to ensure that these provisions also apply to NEMT-PAHPs, as many IHCPs provide their patients with various nonemergency transportation services.
- f. Sections 483.14(b)(2) and (c)(2)—Payment to IHCPs: Proposed §§ 483.14(b)(2) and (c)(2) would implement the payment requirement provisions of ARRA; to address some uncertainty about which payment rates apply, CMS in the final rule should amend these sections to clarify that IHCPs have the right to payment at either the rate set out in the State plan or the encounter rate, whichever is higher.
- **g. Waiver of Referral and Prior Authorization Requirements**: Managed care plans routinely impose referral and prior authorization requirements that do not comport with how IHCPs coordinate care, both within their own health systems and with outside providers through purchase/referred care; to address this issue, CMS should include in the final rule a provision under which MCEs must waive referral and prior authorization requirements for a network primary care provider if the patient receives his or her primary care through an IHCP that applies the same standards.

#### h. Enrollment Protections:

- Monthly Special Enrollment Periods: The proposed rule would allow individuals required to enroll in a managed care program to change plans without cause within 90 days of enrollment in a plan and once every 12 months; to better align Medicaid with enrollment in a QHP—a goal indicated in the preamble—CMS in the final rule should provide monthly special enrollment periods during which Al/ANs required to enroll in a managed care program can opt into a plan or change plans without cause.
- Initial Selection Period: The proposed rule would allow individuals required to
  enroll in a managed care program a minimum period of 14 days between the
  date they are notified that they must enroll in the program and the date on which
  the they become covered by the default MCE; in the final rule, CMS should
  extend this period to 30 days for Al/ANs, many of whom live in remote areas with
  no Internet access and slow mail delivery.
- i. Section 438.71—Beneficiary Support System: Proposed § 438.71 appears to prohibit a Medicaid provider from assisting patients with enrollment in managed care plans; to better align the Medicaid managed care regulations with ACA regulations for Navigators and certified application counselors, CMS in the final rule should clarify that

IHCP participation in a network, or network service area, does not constitute a conflict of interest in assisting patients with enrollment in plans.

- i. Suspension of Payments to a Network Provider: The proposed rule would allow certain MCEs to retain recoveries of overpayments made to providers excluded from Medicaid participation or made as a result of fraud, waste or abuse; to avoid conflicts of interest and foster partnership among CMS, states, MCEs, and providers, in ensuring proper use of the complex Medicaid billing process, CMS in the final rule should revise this provision by requiring affected MCEs to "return to the state any collection of overpayments made to a network provider who was barred from the Medicaid program or the result of fraud, waste, or abuse."
- k. Section 438.10—Information Standards: Proposed § 438.10 would require standardized managed care definitions and terminology and model enrollee handbooks and notices for use by managed care plans, but Al/ANs also need information that clearly states they can continue to access their IHCP whether they in-network or out-ofnetwork and that explains other special protections for Indians; CMS should address this issue in the final rule.
- I. Medicaid Estate Recovery: The proposed rule does not include Medicaid estate recovery—an issue that has meaning for Al/ANs tied to historical trauma and federal Indian law—as one of the topics listed for standardized consumer information for potential enrollees; at a minimum, CMS in the final rule should ensure that potential enrollees undergo a determination process and receive either an exemption from estate recovery or a definitive statement informing them they do not qualify for an exemption.
- m. Section 438.4—Capitation Rates: Proposed § 438.4 would require states to develop capitation rates for MCEs serving Medicaid enrollees in accordance with generally accepted actuarial principles and practices, with the qualifier that any "proposed differences among capitation rates according to covered populations must not be based on the Federal financial participation [FFP] percentage associated with the covered populations"—a provision that might cause uncertainty among states as they attempt to comply and potential confusion among CMS staff as they conduct related enforcement activities, particularly as applied to Indian health care programs; in the final rule, CMS should indicate that a state can develop capitation rates higher than they would set them otherwise as a result of the anticipated enrollment of IHS beneficiaries in the Medicaid managed care plan, including an Indian Medicaid managed care plan.
- n. Tribal Consultation: The proposed rule has the potential to significantly impact both Al/AN access to Medicaid and tribal health care program reimbursement, indicating a need for CMS to work directly with the TTAG and other tribal entities to ensure that the final rule reflects suggestions from Indian Country about minimizing any disruption for individual AI/ANs or Tribes as a whole, but to date no meaningful tribal consultation has occurred; CMS should address this issue prior to the finalization of the rule.

## 14. 70.e. Revisions to PFS and Other Changes to Part B for CY 2016 (CMS-1631-P; comments submitted 9/8/2015 by TTAG)

#### TTAG recommendations

Grandfathered Tribal Federally-Qualified Health Center (FQHC) Status: The proposed rule includes a provision that would withdraw grandfathered Medicare provider-based status for certain tribal facilities and instead offer a new and untested grandfathered tribal FQHC status, a legally unnecessary change that would reverse a nearly two decade history of interpreting and applying the regulation that establishes grandfathered provider-based status and would disrupt operations at the affected tribal facilities, dramatically lower their reimbursement rates, and potentially disqualify them from receiving any Medicare payments between the (unidentified) time they lose their grandfathered provider-based status and the time they qualify for the grandfathered tribal FQHC status; CMS should:

- Eliminate this provision from the final rule; or
- If intent on creating a grandfathered tribal FQHC status, revise the proposed rule to (1) maintain the current reimbursement methodology and rates for facilities changing their status, (2) allow a reasonable transition time and continued provider-based status pending a change to that status, (3) make the status change optional for eligible I/T facilities, (4) clarify several aspects of the rule, and (5) address other tribal concerns.

## 15. 31.aaa. Excise Tax on High Cost Employer Health Coverage (Notice 2015-52; comments submitted 9/30/2015)

### NIHB recommendations

a. Exclusion of Tribal Employers: Internal Revenue Code (Code) section 4980I, which establishes an excise tax on certain employer-sponsored health benefits under which coverage providers must pay a tax on employee plans that exceed certain statutory cost thresholds (excise tax), has the potential to affect the ability of Tribes to structure employee benefit packages in accordance with tribal-specific needs; ACA section 9001. which established section 4980I, excludes Tribes from the list of covered governmental entities and by its terms does not apply to health benefits provided by a Tribe or tribal organization to a member of a Tribe, and as such, IRS should exempt tribal employers that administer their own plans from the excise tax.

Pay and Reimburse Model: IRS proposes a convoluted pay and reimburse model for the excise tax that would impermissibly inflate excise and income tax based liabilities for Tribes far beyond the statutory rate specified in Section 4980I; if the agency decides not to exempt tribal employers that administer their own plans from the excise tax, it should abandon this model both as a matter of law and tax policy in favor of one that allows

employers to calculate and pay the tax themselves on any excess benefits they might provide.

## 16. 89.I. Referrals for Cost-Sharing Protections Under Limited CSVs (CMS/no ref. #; comments submitted 9/30/2015)

#### NIHB recommendations

- **a. Clarification of Documentation Requirements**: CMS should clarify to qualified health plan (QHP) issuers that they cannot make documentation requirements on Indian health care providers (IHCPs) pertaining to limited cost-sharing variation (03/LCSV) plans more rigorous than those outlined in current or subsequent CCIIO guidance documents.
- b. Limitations on Requirements for IHCP Purchased/Referred Care (PRC)
  Programs: CMS should refrain from issuing requirements on IHCP PRC programs
  (except for the recommended requirements below on minimum data elements appearing in a referral for cost-sharing protections) that infringe on the ability and flexibility of IHCPs to continue to manage their PRC programs.
- **c. Flexibility on Referral Types and Forms**: CMS should continue to permit IHCPs to issue a range of referral types and forms, such as a single item or service referral, a referral based on an episode of care, and a comprehensive referral.
- **d. Minimum Data Elements for Referrals**: If determined necessary, CMS should issue revised guidance indicating that the following minimum data elements should appear in a referral for cost-sharing protections from an IHCP:
  - Identification of the patient for whom the referral is issued;
  - Name of the IHCP issuing the referral;
  - · Contact information for the IHCP; and
  - Date of the referral (potentially past the date services were received).

For some PRC referrals for cost-sharing protections, the information above will appear on the referral itself. For other referrals for cost-sharing protections, some of the information (such as the date of referral) is accessed by the QHP issuer contacting the IHCP at the telephone number or e-mail address included on the referral.

#### B. Recommendations Made Prior to Q3 FY 2015 (Since October 1, 2012)

1. 23.b. MACPro: New Online System for State Plan Amendments, Waivers, etc. (CMS-10434; comments submitted 1/22/2013 by TSGAC)

### TSGAC recommendations

#### a. Tribal Consultation:

- The application asks the State (and the State alone) whether State Plan
   Amendments (SPAs) likely would have a direct effect on Al/ANs and Tribal health
   programs, as well as whether the State has complied with Tribal consultation
   requirements; CMS should require States to submit far more extensive
   information regarding consultation.
- CMS has not provided details about repercussions if States indicate they have not engaged in Tribal consultation; if a State clicks "no" when asked about consultation, a graphic should immediately appear notifying the State that it cannot proceed with its application until it engages in consultation.
- If a State clicks "yes" when asked about Tribal consultation, it must submit only limited information; CMS should require states to:
  - Provide a specific list of Tribal participants in each consultation session listed on the application and the topics of discussion (including a copy of the minutes);
  - o Provide a summary of all comments received during the Tribal consultation;
  - Upload any documents submitted by Tribal entities during the consultation process;
  - Describe the specific State response to the Tribal submissions (including relevant documents or correspondences); and
  - Provide details regarding what areas are not agreed upon during the consultation, the process for resolving the issue(s), and potential resolutions discussed.
- MACPro asks whether a State "has solicited advice from Tribal governments
  prior to submission of this SPA application," but § 5006 also requires consultation
  with "Indian Health Programs and Urban Indian Organizations"; as a point of
  clarification, CMS should add the phrase "Indian health programs and Urban
  Indian organizations" after the phrase "Tribal governments."

#### b. Access to Proposed SPAs and Comments:

 Only State or CMS officials can access the MACPro system, and although MACPro will send public information regarding Medicaid and CHIP eligibility coverage to Healthcare.gov and Medicaid.gov, the details of this process remain

- unclear; CMS should make proposed SPAs, waivers, and similar materials available to I/T/Us in real-time to maximize Tribal participation and help encourage States to engage in proactive consultation.
- States also do have to submit to CMS comments on SPAs received during public comment periods or Tribal consultation; CMS should require states to submit all comments and post them on MACPro.
- CMS also should ensure that: (1) I/T/Us have access the MACPro database to
  monitor proposed SPAs and associated application materials (even if solely in a
  "read-only" mode) and/or (2) whatever "public information" that CMS plans on
  making available via Healthcare.gov include both materials submitted by the
  State as well as applicable Tribal and general comments.

### c. CMS Point of Contact and Review Team:

- The "CMS point of contact and review team" will make decisions on approval of applications, but how this team will determine States engaged in adequate Tribal consultation remains undetermined; CMS should CMS consult with Tribes and Tribal organizations, to develop guidelines or policies that this team can use to evaluate the sufficiency of Tribal consultation.
- The CMS officials who can serve as a point of contact or on the review team remain undetermined; when a State subject to the Tribal consultation requirements in § 5006 submits a SPA or a waiver request, the CMS point of contact and/or review team should include at least one individual who is either:

   (1) a member of the CMS Tribal Affairs Group or (2) has a demonstrable background in or familiarity with the Indian health system.

## 2. 50.k. Model Eligibility Application (CMS Guidance Document/no ref. #; comments submitted 5/23/2013 by TTAG)

- a. Cover page: "Who can use this application?"-
  - The Short Form informs Al/ANs that they cannot use it to apply, but neither of the other two other applications tells Al/ANs that they should use it to apply; if CMS intends for Al/ANs to use the Application for Health Coverage & Help Paying Costs—to which it has attached Appendix B, "American Indian or Alaska Native Family Member (Al/AN)"—it should clarify this in the cover page.
  - CMS should allow single adult Al/ANs to use the Short Form with Appendix B, which is a stand-alone page.

### b. Appendix B-

- Title: The title, "American Indian or Alaska Native Family Member (Al/AN)," might cause confusion when individuals apply as individuals and not in a family plan because, even though the language below the title reads, "Complete this appendix if you or a family member are American Indian or Alaska Native," individuals might believe they have to provide information about their parents to establish their qualification as Indian, even if they do not seek health insurance for their parents and their parents do not live in the same household; CMS should clarify this language.
- Second paragraph: This paragraph, which attempts to explain why AI/ANs should identify themselves and complete this form, has a number of issues; CMS should remove the "s" from the end of Indian Health Services, clarify that individuals who enroll in health plans through the Exchange/Marketplace can continue to receive care from the I/T/U, clarify that cost-sharing and special enrollment periods apply specifically to AI/ANs; revise the condescending and culturally inept phrase "make sure your family gets the most help possible," which indicates welfare and dependency, rather than entitlement to certain provisions and protections under the law.
- Question 3: This question begins, "Has this person ever gotten ..." To avoid awkwardness, CMS should change this question to begin, "Has this person ever received ..."

#### Question 4:

- The "How often?" that appears in this question might cause confusion; CMS should change this part of the question to read, "Since January 1, 2012, did you receive ..."
- This question, unlike the others, does not have a box to check for "no," assuming applicants have income to report. CMS should add box to address this possibility of no income.
- The phrase "reported on your application" in this question seems threatening, rather than helpful; CMS should frame this part of the question as: "There are special rules that allow American Indians and Alaska Natives to qualify for Medicaid and CHIP. If you have income from some sources, it is not counted for Medicaid and CHIP eligibility. We will use the information you provide here to reduce your income on your Medicaid and CHIP applications. Please list any income that you reported on your federal income tax that relates to the following ..."

## 3. 23.c. Tribal Consultation State Plan Amendment Template (CMS-10293; comments submitted 7/23/2013 by TTAG)

### TTAG recommendations

- **a. Sufficient Tribal Consultation**—CMS-10293 asks States to indicate whether they have in place a tribal consultation structure, not a process; CMS should include in the form additional reporting items related to applicability, timing, and sufficiency of consultation (listed below) to document that States actually solicited and considered advice:
  - What items in this proposal (State Plan Amendment, waiver, or Demonstration Project proposal) are likely to have a direct effect on Indian health care providers?
  - How and when were Indian health providers notified about this issue?
  - Were Indian health providers given a description of the potential impact of the proposed change?
- **b. Tribal Access to Information**—Tribes and urban Indian organizations should have the ability to review the information provided by States and offer alternative perspectives on the process; CMS should publish the State Plan Amendment, including CMS-10293, on the agency Web site and should accept comments and objections from Tribes and Indian health care provider organizations.

## 4. 153.g. CMS/IRS Computer Matching Program (CMS/no ref. #; comments submitted 9/13/2013 by TTAG)

### TTAG recommendations

### **Identification as Indian in Return Information**:

- IRS should explicitly indicate that the Return Information identifying an individual
  as an Indian under IRC § 45A(c)(6), if any, will appear in the Return Information
  disclosed by IRS to CMS and by CMS to an Administering Entity for purposes of
  conducting eligibility determinations for cost-sharing reductions under section
  1402 of ACA; and
- CMS should provide the information on Indian status, along with other Return Information, to an Administering Entity (state agencies that administer Medicaid or CHIP and state-based Exchanges and Marketplaces) through the CMS Data Services Hub for the purpose of determining eligibility for Insurance Affordability Programs.

## 5. 99.b. Nondiscrimination in Certain Health Programs or Activities (HHS OCR/RIN 0945-ZA01; comments submitted 9/30/2013)

### TTAG recommendations

**Exemption**: The exemption for Indian health services in Title VI of the Civil Rights Act of 1964 recognizes the special Federal trust relationship with Indians and the special nature of the Indian health services program rooted in that relationship; CMS should reaffirm this exemption in any Section 1557 regulations.

# 6. 168. Enrollee Satisfaction Survey Data Collection (CMS-10488; comments submitted 12/2/2013)

#### NIHB/TTAG recommendations

- **a. Questions Specific to Al/ANs—Marketplace Survey**: To address questions specific to the experiences of Al/ANs, CMS should include a section titled "American Indians and Alaska Natives and Other Individuals Eligible to Receive Services from an Indian Health Care Provider," which should solicit responses to the below questions.
  - Whether the Marketplace provides specific information on how it determines "Indian" status for both Medicaid and QHPs, as well as the process by which an individual can challenge an unfavorable determination;
  - What types of documents that the Marketplace accepts as proof of Al/AN status, as well as the ease of uploading or otherwise providing these documents;
  - Whether the Marketplace informs AI/ANs of their eligibility for a special monthly enrollment period;
  - Whether the Marketplace explains (1) the existence of Al/AN-specific costsharing protections under both QHPs and Medicaid; (2) the differences in eligibility for cost-sharing protections in QHPs compared with Medicaid; and (3) the manner in which an Al/AN can establish eligibility for any relevant costsharing protection;
  - Whether the Marketplace specifically explains (1) how AI/ANs and IHS-eligibles
    can apply for exemptions from the shared responsibility payment; the differences
    in the exemption process for members of federally recognized Indian tribes and
    shareholders in Alaska Native Regional or Village Corporations as compared to
    IHS-eligibles; and (3) the actual process for obtaining the exemptions; and
  - What interaction the AI/AN individual has experienced with any enrollment assisters or similar Marketplace personnel concerning AI/AN-specific enrollment issues.

**b. Al/AN Survey Responses**: To address concerns about an inadequate survey response rate from Al/ANs, CMS should designate a portion of the annual funding for the Marketplace and QHP surveys for grants or contracts to tribes, tribal organizations, and/or I/T/Us to conduct the data collection in person in Al/AN communities.

## 7. 111.c. Request for External Review (OPM/OMB 3206-xxxx; comments submitted 12/23/2013 by TTAG)

- **a. Information Specific to Al/ANs**: To ensure Al/ANs know about special protections that apply to them, OPM should:
  - Add the following provisions to the Model Notice of Final Internal Adverse Benefit Determination:
    - A statement that members of an Indian tribe or Alaska Native Claims Settlement Act (ANCSA) corporation qualify for cost-sharing exemptions under ACA; and
    - A statement that an Indian (as defined) who believes a plan has erroneously assessed him or her cost sharing can contact OPM, along with the relevant contact information and/or link to the Case Intake Forms.
  - Add the following provisions to the Case Intake Forms:
    - i. An explanation of the two cost-sharing exemptions and the different category of Indian to which each applies;
    - o A definition of "cost-sharing" for the purposes of the exemptions; and
    - An explanation of the procedure in which an Al/AN can challenge the adverse determination, including the list of relevant documentation that he or she might use to establish eligibility for the cost-sharing exemptions.
- **b.** Availability and Submission of the Case Intake Forms: To maximize flexibility for AI/ANs, many of whom lack Internet access, OPM should make the Case Intake Forms available as paper, online, and electronic documents.
- **c. Alternate Language Options**: OPM should ensure that both of the proposed forms offer assistance in Navajo and Yupik, the most commonly spoken languages among Al/ANs, and consult with TTAG concerning arrangements for primary speakers of other Al/AN languages.
- **d. Tribal Consultation**: OPM should consult with TTAG concerning the actual language of these provisions in both of the proposed forms.

## 8. 184.a. Clinical Laboratory Improvement Amendments Regulations (CMS-R-26; comments submitted 1/6/2014 by ANTHC)

#### ANTHC recommendations

- a. Burden Estimates—CMS should:
  - Increase the burden estimates assigned to enrollment and successful participation in proficiency testing (PT) to reflect practical experience and to recognize special circumstances (e.g., limited federal funding, remote lab sites, and transient employees) affecting IHS and tribal health programs; and
  - Clarify the burden estimate for each step in the PT process (i.e., receipt and handling, testing, reporting, and director review/analysis) to facilitate the accuracy of information collection pertaining to PT, as without these changes, the agency will continue to underestimate the difficulty and time required for laboratories (particularly IHS and tribal facilities) to comply with reporting requirements.
- b. CLIA Reporting Process—CMS should initiate a formal rulemaking procedure with an associated Notice and Comment period to substantively amend and streamline the CLIA reporting process; through this procedure, to lessen the burden of IHS and tribal facilities in meeting competency assessment requirements and increase the relevance of these requirements to evaluate competency of all testing personnel, the agency should:
  - Develop an alternate option for competency assessment, similar to the recent alternate quality control option allowed by 42 CFR § 493.1250; and
  - Include exceptions for actions falling under § 493.1840(b) or its amendments to allow lesser penalties that will not impact the CLIA certificate(s) of the laboratory director.
- 9. 31.v. Instructions for the Application for Indian-Specific Exemptions (CMS/no ref. #; comments submitted 1/13/2014 by TTAG)

### TTAG recommendations

a. Page 1, First Bullet and Step 2, Item 7: CMS should add language to the instructions for these items to clarify that "member of an Indian tribe" includes Alaska Native village members and Alaska Native Claims Settlement Act (ANCSA) shareholders.

- **b. Step 2, Item 8**: To address concerns that non-pregnant AI/AN women eligible for a Regulatory Hardship Exemption will not understand they should complete more of the application, CMS should emphasize the word "only" in the instructions for this item.
- **c. Step 2, Items 10 and 11**: CMS should change the language in the instructions for these items and add examples to clarify how to complete these questions on the application; alternatively, the agency could add an introduction that reads, "If you are an AI/AN and eligible for services from an Indian Health Care Provider even if you are not pregnant and without regard to your marital status, age, or place of residence, you do not need to respond to Items 10 or 11."
- **d.** Step 2, Items 7, 8, 9, and 10 and Introduction to the Tables, Second Paragraph: For clarification purposes, CMS should change all instances of "you're" to "you are" in the instructions for these items.
- **e. Introduction to Tables, Second Paragraph**: CMS should add the word "only" to the second sentence in this paragraph to emphasize that applicants who can supply the documents listed in Table 1 do not have to supply the documents listed in Table 2; in addition, in the introduction to Table 1, CMS should avoid emphasis on the "Federally recognized tribe" language to prevent confusion about which exemption applies to ANCSA shareholders.
- **f. Table 1, Rows 1 and 2**: CMS should add a reference in these rows to the Certificate of Degree of Indian Blood (CDIB), which the Bureau of Indian Affairs (BIA) or a Tribe can issue and which often serves as the only form of proof of tribal membership to which AI/ANs have access.
- **g. Table 1, Row 3**: CMS should revise this row to describe fully the categories of Indians entitled to health care services provided by IHS under the Indian Health Care Improvement Act.
- 10. 50.t. QHP Quality Rating System Measures and Methodology (CMS-3288-NC; comments submitted 1/21/2014 by TTAG)

- **a. Information on Access to I/T/U Providers**: To address the need for timely and accurate information on the inclusion of I/T/U providers in qualified health plan (QHP) networks, CMS should add the following individual QRS measures:
  - Number of I/T/U providers in the geographic area served by the QHP;
  - Number of I/T/U providers in the geographic area served by the QHP considered in-network providers; and

- Percentage of I/T/U providers in the geographic area served by the QHP considered in-network providers.
- **b. Information on Al/AN Member Experience**: To ensure that QHPs help Al/ANs understand and obtain the many Al/AN-specific protections provided by ACA, TTAG, in comments filed on December 2, 2013, recommended that CMS add to the QHP Enrollee Survey an Al/AN-specific section with a number of topics, and by adopting these recommendations, CMS will have the information necessary to add the following individual QRS measures:
  - Percentage of Al/AN members who are aware of the availability of I/T/Us as innetwork providers in the QHP;
  - Percentage of claims denied by the QHP, in full or in part, for services provided at an I/T/U;
  - Percentage of Al/AN members who have ever had cost sharing in any circumstances in which ACA exempts them;
  - Percentage of Al/AN members who have entered disputes with the QHP over cost sharing, as well as the percentage of resolved disputes; and
  - Percentage of Al/AN members who positively rate their experience with QHP personnel.
- **c. Al/AN-Specific CAHPS Measures**: QRS, as proposed, includes 13 Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey measures, but these measures might not reflect the special circumstances and needs of Al/ANs; the American Indian Survey—which CAHPS developed in 2004-2005 to help establish benchmarks for Al/AN patient experiences, whether at I/T/U or non-I/T/U facilities—produces a number of Al/AN-specific measures, and CMS should add these measures as individual QRS measures.

# 11. 23.g. Imposition of Cost-Sharing Charges Under Medicaid (CMS-R-53; comments submitted 3/17/2014 by TTAG)

### TTAG recommendations

To facilitate the successful development of procedures that would effectively implement and enforce the exclusions from cost sharing for certain Al/ANs found in current regulations, CMS should—

**a. Template**: Develop a template (or templates) of procedures to implement and enforce the Indian-specific exclusions from cost sharing and allow states to adopt this template or develop alternative approaches, a policy that likely would expedite

implementation of approaches effective in providing protections to AI/ANs and minimize the burden placed on states, providers, health plans, and enrollees.

- **b. Self-Attestation**: Incorporate into the template an option for self-attestation of eligibility as an American Indian or Alaska Native, a policy that would streamline the process for eligibility determinations and eliminate the likelihood that paperwork requirements would impede individuals from accessing the protections for which they qualify.
- **c. Indian Identifier**: Continue and complete ongoing efforts to modify state Medicaid Statistical Information Systems to capture an identifier for individuals determined to qualify for the Indian-specific cost-sharing protections, including assisting states with adoption of the new functionality.
- **d. Electronic Data Matching**: Include in the template a mechanism for electronic data matching (potentially through the IHS National Data Warehouse) to proactively identify individuals eligible for Indian-specific cost-sharing protections, a policy that would increase the number of eligible individuals who receive these protections, given their lack of familiarity among AI/AN enrollees (and possibly state Medicaid agency caseworkers).

## 12. 188. Emergency Preparedness Requirements (CMS-3178-P; comments submitted 3/31/2014 by TTAG)

- **a. Impact on Tribes and Indian Health Programs**—To acknowledge the challenges that this proposed rule will pose for Tribes and Indian health programs, CMS should:
  - Perhaps collaboratively with other federal agencies, provide training for Tribes and Indian health programs regarding current emergency preparedness laws and directives and their roles in satisfying these laws and directives;
  - Perhaps collaboratively with other federal agencies, offer on- site technical assistance and other support to Indian health programs that need help obtaining the necessary collaboration of non-Indian health providers and state and local of governments; and
  - Schedule consultation with Indian health programs, in conjunction with TTAG, about how the new requirements will affect various provider types and adopt provisions for delayed implementation of the requirements in Indian health care facilities until adequate consultation and training occur.
- b. Alternative Approaches to Implementation—CMS should:

- Allow providers to obtain waivers of the deadlines and of specific requirements, if the provider has a minimal plan for compliance within its proposed timeline, because one year might not provide adequate time for some providers to become familiar with all of the new requirements and to implement them.
- Allow providers to establish their own training exercise schedule based on local conditions, because with the large variation in the types of facilities and the conditions under which they operate, "one-size-fits-all" training will not necessarily achieve the best outcome.
- When the same owner administers multiple facility types (a common practice
  among Indian health programs), allow the facilities to obtain waivers of specific
  requirements or have a single, multi-facility plan approved, if they can collectively
  adopt a functionally equivalent strategy based on the requirements that might
  apply to one of their other facility types—as proposed, this rule would require
  each of these facility types to meet certain specific requirements, a policy that
  might lead to duplicative, and ultimately confusing, emergency protocols; and
- Offer facilities an opportunity to review their existing policies and procedures and seek approval for continuing to rely on them instead of implementing the new requirements, if the facility can demonstrate that this would achieve a substantially similar outcome, with deadlines for compliance with any new requirements applied only after a review of the continuation plan.

# 13. 65. Health Care Reform Insurance Web Portal Requirements (CMS-10320; comments submitted 5/12/2014 by TTAG)

- a. Information Availability: Requiring health insurance issuers to provide information on the QHP offerings available to Al/ANs through the Marketplace Web portal, as well as requiring both issuers and Marketplaces to post or link to this information on their respective Web sites, would help address a significant barrier to Al/AN enrollment in the QHPs; in setting the parameters for the information issuers must submit to the Web portal and the subsequent dissemination of this information, CMS should:
  - Require issuers to submit to the Marketplaces an explanation that AI/ANs can
    enroll in all QHPs offered and that each of these QHPs has a zero cost-sharing
    plan variation and a limited cost-sharing plan variation specifically for AI/ANs,
    with the distinctions between these plans indicated;
  - Require Marketplaces to create a template Summary of Benefits and Coverage (SBC) for the zero cost-sharing plan variation and the limited cost-sharing plan

variation to identify the cost-sharing protections and how they generally apply to covered services;

- Create a template for use by QHP issuers and require them to populate it
  template with information on each zero and limited cost-sharing plan variation
  and provide access to the SBC to potential QHP enrollees by making the costsharing variation-specific SBC accessible on their Web sites that display the
  QHP options without requiring the use of passwords or other barriers (and
  require Marketplaces to list this information on their Web sites); and
- Require issuers to provide proactively the cost-sharing-specific SBC to enrollees within seven days of receiving an application from a potential enrollee.

## 14. 50.x. Third Party Payment of QHP Premiums (CMS-9943-IFC; comments submitted 5/13/2014 by TTAG)

#### TTAG recommendations

This Interim Final Rule ensures that I/T/Us will not face continued problems by requiring QHPs to accept aggregated premium payments and imposing civil penalties if QHPs reject these payments; specifically, TTAG indicated strong support for the following provisions:

- a. The added requirement on QHPs in 45 CFR § 156.1250: This provision reads: "§ 156.1250 Acceptance of certain third party payments. Issuers offering individual market QHPs, including stand-alone dental plans, must accept premium and cost sharing payments from the following third-party entities on behalf of plan enrollees: (a) Ryan White HIV/AIDS Program under title XXVI of the Public Health Service Act; (b) Indian tribes, tribal organizations or urban Indian organizations; and (c) State and Federal Government programs."
- **b. The strengthened enforcement provision in § 156.805**: This provision now includes that failure to comply with the requirement to accept third party payments in accordance with § 156.1250 could constitute a violation of § 156.805(a)(1) as "substantial noncompliance with [an] Exchange standard[]."

## 15. 92.w. Provider Non-Discrimination (CMS-9942-NC; comments filed 6/10/2014 by TTAG)

#### TTAG recommendations

**a. Excluding or Discriminating Against Entire Provider Types:** Section 2706(a) seeks "to ensure that patients have the right to access covered health services from the full range of providers licensed and certified in their State," but the FAQ indicates that

this section "does not require plans or issuers to accept all types of providers into a network," a statement that would undercut an important statutory protection and could disproportionately disadvantage I/T/U providers; the agencies should interpret Section 2706(a) as prohibiting group health plans and health insurance issuers from systematically excluding "whole categories of providers operating under a State license or certification" from their networks and restricting provider reimbursement or network inclusion according to the type or location of the facility or service site of the provider.

- **b. Discriminating Based on Marketplace Factors:** Section 2706(a) authorizes health insurance issuers to establish "varying reimbursement rates based on quality or performance measures," but the notice adds that issuers can discriminate based on "market standards"; the agencies should interpret Section 2706(a) as prohibiting discrimination based on market standards, as it could negatively impact providers by aggravating an existing problem in which issuers limit or reduce payments for certain provider types that do not work in specific facilities.
- **c. Discriminating Against Certain I/T/Us**: The agencies should recognize that health insurance issuers cannot discriminate against I/T/Us that choose to recover under the terms of Section 206 of the Indian Health Care Improvement Act and that, when Marketplace issuers offer network contracts to I/T/Us as required by CCIIO, these contracts must include payment rates at least equal to generally applicable rates for innetwork providers.

## 16. 188.b. Fire Safety Requirements for Certain Health Care Facilities (CMS-3277-P; comments submitted 6/16/2014 by TTAG)

- **a. Occupancy Standards**: CMS should clarify the scope of occupancy standards in the proposed rule, and in the case of hospitals, apply these requirements to the hospital itself, not off-site facilities billing under the hospital provider number; if the agency does intend to apply these standards to all facilities billing under a hospital provider number, it should extend the comment period to allow hospitals and other facilities more time to properly respond.
- **b. Timeframe for Implementing Evacuation/Fire Watch Procedures**: The proposed rule would require evacuation or a fire watch when a sprinkler system remains out of service for more than 4 hours, rather than 10 hours as recommended by the National Fire Protection Association (NFPA) Life Safety Code (LSC) 2012 edition; CMS should extend the timeframe to 10 hours, a standard that would ensure proper monitoring of facilities but would not implement expensive and burdensome evacuation/fire watch procedures without good cause.

- **c. Smoke Exhaust Systems in Operating Rooms**: The proposed rule would mandate that facility operating rooms (ORs) contain smoke exhaust systems, a requirement eliminated in the 2012 edition of the LSC after NFPA determined that hospitals no longer use flammable anesthetics and have limited the presence of any combustibles in ORs; CMS should remove this requirement.
- **d. Window Requirements**: The proposed rule would require that every health care occupancy patient sleeping room have an outside window or outside door with a sill height not to exceed thirty-six inches above the floor, although NFPA eliminated this standard in the 2012 edition of the LSC; CMS should remove this requirement or at least clarify that it applies only to new construction and not existing facilities, as requiring existing facilities to retrofit their occupancy rooms could result in a significant expense for comparatively little reward in terms of increased safety.

# 17. 185.c. Revisions to HHS OIG Exclusion Authorities (HHS OIG/RIN 0936-AA05; comments submitted 7/8/2014 by TTAG)

- a. \$10,000 Daily Civil Monetary Penalty (CMP) for Unreturned Overpayments: HHS OIG seeks comment on whether it should impose a CMP of as much as \$10,000 for each day that a provider fails to return an overpayment or whether it should instead impose the default penalty of as much as \$10,000 for each individual claim identified as an overpayment; HHS OIG should impose the latter penalty, as a \$10,000 daily penalty could prove ruinously expensive for tribal health programs, which already struggle with drastic federal underfunding.
- b. Exemption of IHS Programs from the Proposed Expansion of the Loan Default Regulations: HHS OIG, which has the authority to exclude providers from federal health care programs if they "default on repayments of scholarship obligations or loans in connection with health professions education made or secured, in whole or in part, by the Secretary," proposes to apply this exclusion to individuals who default on a number of additional federal repayment and loan programs, including those offered by IHS; HHS OIG should exclude IHS scholarship and loan repayment programs from the expanded scope of the loan default regulations, as including these programs would make filling the employment gaps in tribal and other rural providers even more difficult.
- c. Potential Regulation to Protect Rural Patients: In the proposed rule, HHS OIG notes that CMS has the authority to pay claims submitted by an enrollee in Medicare Part B, if otherwise payable, when an excluded provider furnishes the items or services, if the enrollee does not know or have reason to know of the exclusion and proposes to extend this authority to claims submitted by enrollees in Medicare Parts C and D. However, HHS OIG raises concerns that, because the statute applies only to Medicare enrollees who submit claims directly—a rare practice, especially in Part D—some

enrollees might not have the ability to access to needed services due to the exclusion of their provider and requests comments on how, within the law, it could craft a regulation to protect these enrollees in this limited circumstance; OIG should make the following edits to 42 C.F.R. § 1001.1901(c):

42 C.F.R. § 1001.1901(c) Exceptions to paragraph (b)(1) of this section.

(1) If an enrollee of Part B of Medicare submits an otherwise payable claim for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual after the effective date of exclusion, CMS will pay the first claim submitted by the enrollee and immediately notify the enrollee of the exclusion. In cases where the excluded individual or entity's submission of claims would invalidate payment for an emergency item or service or one that the enrollee cannot reasonably obtain from a non-excluded individual or entity, the provider may assist the enrollee in submitting the claim directly.

. . .

- (5)(i) Notwithstanding the other provisions of this section, payment may be made under Medicare, Medicaid or other Federal health care programs for certain emergency items or services furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician or other authorized individual during the period of exclusion. To be payable, a claim for such emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services specifying the nature of the emergency and why the items or services could not have been furnished by an individual or entity eligible to furnish or order such items or services. whether due to a medical emergency, a patient's geographical or financial inability to obtain medically-necessary services from a non-excluded provider, or other circumstances within the scope of the individual or entity's professional judgment.
- **d. Proposed "Early Reinstatement" Provisions**: HHS OIG proposes to allow reinstatement of providers excluded from federal health programs due to adverse licensing determinations under certain circumstances; in the final rule, HHS OIG should retain this proposal, which would help with filling the employment gaps in tribal and other rural providers.
- 18. 185.e. Potential Revisions to Criteria for Permissive Exclusion Authority (OIG-1271-N; comments submitted 9/9/2014)

#### TTAG recommendations

**a.** Addition of Sole or Primary Community Provider Status to Criteria—The Criteria directs HHS OIG to consider whether a permissive exclusion of a defendant that "is an entity" would prevent the entity from "being able to operate without a real threat of bankruptcy and without a real threat to its ability to provide quality health care items or

services," but this standard appears inadequate in the tribal health context; HHS OIG should consider whether the entity at issue serves as the "sole or primary source of health care services in a community" when determining whether to impose a permissive exclusion.

- b. Tribal Consultation in Developing Standards Applicable to Tribal Governments—HHS OIG has offered at least one Tribe a "Tribal Integrity Agreement" (TIA) as a precondition for avoiding a permissive exclusion, and the agency drafted this agreement, which appears essentially the same the Corporate Integrity Agreement used with non-governmental health care facilities, without undertaking tribal consultation or considering the structural and functional differences between a general health care facility and one operated by a tribal government; HHS OIG should consult with Tribes concerning the terms, scope, and application of TIAs, as significant changes are needed to ensure continued tribal participation in federal health programs.
- **c.** Tribal Consultation in Develop Strategies for Preventing Compliance Issues at I/T/Us—HHS OIG should not take enforcement actions against I/T/Us based on unintentional compliance issues indentified during preliminary audits and instead should work with I/T/Us to resolve these issues and prevent their reoccurrence, as well as establish proactive compliance, education, outreach, and troubleshooting programs developed in consultation with CMS and Tribes.

# 19. 29.g. Payment Collections Operations Contingency Plan (CMS-10515; comments submitted 9/25/2014)

## NIHB/TTAG recommendations

To better promote issuer and enrollee understanding of ACA provisions on AI/AN eligibility for either a "zero cost-sharing plan variation," CMS should include a short statement on the Indian-specific cost-sharing protections when describing the general cost-sharing protections in this notice.



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		EXCHANGE/OTHER HEALTH R	EFORM ISSUES		
2016 Letter to Issuers in FFMs	7.w./ CCIIO (no reference number)	<ol> <li>Application of Requirements Related to Indian Health Providers (IHPs): The requirements in the 2016 Issuer Letter apply solely to issuers when offering qualified health plans (QHPs) through the Federally-Facilitated Marketplace (FFM); CMS should extend these requirements to issuers when offering QHPs in State-Based Marketplaces.</li> <li>Requirement for Issuers to Offer Contracts to IHPs: The draft 2016 Issuer Letter does not retain a provision in the 2015 Issuer Letter (page 20) requiring issuersin cases in which they fail to meet the 30 percent essential community provider (ECP) guidelineto attest in a narrative justification to having made good faith contract offers to all IHPs in a QHP service area and instead states on page 26, "If an issuer's application does not satisfy the 30 percent ECP standard as well as the requirement to offer contracts in good faith to all available Indian health providers in the service area," the issuer must provide a narrative justification (emphasis added); CMS should delete the italicized phrase, as it would allow an issuer to offer a QHP through the FFM without having made good faith contract offers to all available IHPs.</li> </ol>	1. NO 2. NO	1. NO 2. NO	<ol> <li>Application of Requirements Related to Indian Health Providers (IHPs): Not accepted. CCIIO did not address this issue.</li> <li>Requirement for Issuers to Offer Contracts to IHPs: Not accepted. CCIIO did not address this issue.</li> </ol>



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ECP Data Collection to Support QHP Certification for PY 2017	7.ddd./ CMS-10561	<ol> <li>Attestation to Imposition of Sliding Fee Scale: The Instructions linked to this PRA notice list a number of statements to which provider petitioners must attest to qualify as an ECP, including "Provider accepts patients regardless of ability to pay and offers a sliding fee schedule," but Indian health care providers (IHCPs) do not impose a sliding fee scale on IHS beneficiaries; CMS should:</li> <li>Indicate it will not impose the requirement to offer a sliding fee schedule on IHCPs as a condition for inclusion on the HHS ECP List; or</li> <li>Add a question as to whether a provider is an IHCP and, if yes, indicate that the IHCP does not have to meet the requirement to offer a sliding fee schedule.</li> </ol>	1. NO	1. NO	Attestation to Imposition of Sliding Fee Scale: Not accepted. CMS did not address this issue.   Attestation to Imposition of Sliding Fee Scale: Not accepted. CMS did not address this issue.
		2. Window to Update HHS ECP List: As indicated by CCIIO representatives, between October 23, 2015, and November 23, 2015, CMS plans to open the Petition for providers to make corrections and updates to their entries on the HHS ECP List, but this one-month window might not allow sufficient time for the hundreds of non-IHS ICHPs to access and update their information through the Petition; CMS should:	2. <b>NO</b>	2. YES	2. Window to Update HHS ECP List: Accepted in part. In response to the request for a grace period or a transition year prior to removing otherwise qualified providers from the HHS ECP List, CMS stated that it will consider this comment.



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		<ul> <li>Consider extending the timeframe for making updates to the HHS ECP List;</li> <li>Prior to excluding current IHCPs on the HHS ECP List, undertake proactive efforts to contact individual providers to inform them of the need to update their entry or entries on the HHS ECP List;</li> <li>Prior to excluding current IHCPs on the HHS ECP List, provide a list of the IHCPs that have failed to update their entry or entries to the Tribal Self-Governance Advisory Committee to IHS, the TTAG, and/or IHS to allow proactive outreach by these organizations; and/or</li> <li>Provide a six-month grace period after the November 23, 2015, deadline prior to removing any IHCPs from the HHS ECP List</li> </ul>			
		3. Required Inclusion of National Provider Identifier: According to the Instructions, the data fields for which providers on the HHS ECP List must provide correct information include "National Provider Identifier" (NPI) and two other fields, and a review of the Draft 2017 HHS ECP List shows that none of the providers currently on the list have information listed for these fields, indicating that all of these providers will have to complete the Petition to remain on the list for PY 2017; at least with regard to NPI	3. NO	3. YES	3. Required Inclusion of National Provider Identifier: Accepted in part. CMS stated that "providers must directly petition to consent to be included or remain on the HHS ECP list, even if HHS has obtained the required provider data from a Federal partner." However, according to CMS, "if any of the above entities own or are the authorized legal representatives of an ECP then they may submit a petition on behalf of a provider."



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		numbers, CMS should populate this field with data provided directly from IHS for each IHCP.  4. Required Data: In addition to the three data elements identified above, CMS has indicated it might consider identifying additional data elements as "mandatory" fields, with failure to populate these fields resulting in the removal of a current entry on the HHS ECP List, but dropping an existing	4. NO	4. YES	4. Required Data: Not accepted. According to CMS, "HHS believes that the required data fields in the petition are critical to the ability of HHS to review for issuer compliance with the ECP standard."
		ECP entry for not supplying non-critical information seems out of proportion with the benefit of providing the information, possibly leading to counterproductive results by unnecessarily excluding ECPs, particularly IHCP ECPs; CMS should limit the identification of "required" or "mandatory" data elements that could result in exclusion of ECPs from the HHS ECP List to only those data elements critical to the ability of the agency to operate the ECP program.  5. Maintenance of Requirement to Offer to Contract with IHCPs: CMS has indicated that it will exclude from the HHS ECP List ECPs not providing all the required data elements, and given that the ECP contracting requirements appear tied to the HHS ECP List, a failure to appear on the HHS ECP List might impede or eliminate the right an ECP to the ECP protections in ACA; CMS should clarify in the Petition, CCIIO Issuer Letter, and other appropriate documents that an IHCP retains its right to receive (and to accept) a contract offer from	5. <b>NO</b>	5. <b>NO</b>	5. Maintenance of Requirement to Offer to Contract with IHCPs: Not accepted. CMS did not address this issue.



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		a QHP meeting the minimum standards even if the IHCP does not appear on the HHS ECP List.			
MEC and Other Rules on the Shared Responsibility Payment	31.x./ TD 9705	1. Streamlined Process to Establish Avenue for Claiming Additional Hardship Exemptions: The proposed rule includes a provision that would establish a streamlined regulatory process in § 1.5000A-3 of the Internal Revenue Code under which IRS could accept a delegation of authority from HHS to allow an individual to claim an additional type of hardship exemption through the Federal tax-filing process without first obtaining a hardship exemption through a Marketplace; IRS should:   a. Retain this provision in the final rule; and  b. In the preamble to the final rule, cite as a potential example of the use of this streamlined process the expedited establishment of authority for individuals to apply for and claim the Indian health care provider-eligible exemption through the Federal tax-filing process.	1. a. YES 1. b. YES	1. a. N/A 1. b. N/A	<ul> <li>Streamlined Process to Establish Avenue for Claiming Additional Hardship Exemptions:</li> <li>a. Accepted. IRS addressed this issue as recommended.</li> <li>b. Accepted. IRS addressed this issue as recommended.</li> </ul>
Health Coverage Exemptions	31.bb./ Form 8965	Instructions on Completing Parts I, II,     and III: IRS should indicate on the form     (not just in the instructions) that individuals	1. NO	1. <b>NO</b>	Instructions on Completing Parts I, II, and III: Not accepted. IRS did not address this issue in the final form.

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		can complete either Part I or Part II or Part III; without this information, individuals might think they have to complete both Parts I and III.  2. Recognition of ANCSA Corporation Shareholders: On page 2 of the instructions, the 6th row in the chart reads: "Members of Federally-recognized Indian Tribes—You are a member of a Federally-recognized Indian tribe"; IRS should add to this entry, "including an Alaska Native Claims Settlement Act (ANCSA) Corporation Shareholder (regional or village)."	2. YES	2. N/A	Recognition of ANCSA Corporation     Shareholders: Accepted. IRS addressed this issue as recommended.
		3. Use of the Term "Alaska Native": When using the term, "Alaska Native", as in the tables on page 2 and on page 12 showing exemption types of coverage, Code E, IRS should capitalize "Native," as the term "Alaska native" refers to any individual born in Alaska.	3. YES	3. N/A	Use of the Term "Alaska Native":     Accepted. IRS addressed this issue as recommended.
		4. Consolidation of Al/AN-Related Information: IRS should gather all of the information related to Al/ANs and place it in one location in the instructions to help Al/ANs understand the complete picture and allow Tribes to copy and distribute the information to assist individuals in filling their tax returns; specifically, IRS should combine the instructions on page 10 for members of federally-recognized Tribes with the instructions on page 12 for IHS-eligible individuals and, on page 10 at the end of the sentence under "Member of a Federally-	4. YES	4. N/A	Consolidation of Al/AN-Related Information: Accepted. IRS addressed this issue as recommended.



Issue	Related RRIAR Ref. #/ File Code	Summary of Tribal Entity Recommendations	Addressed Issue as Recommended	Acknowledged Issue and/or Addressed by Other Means	Action Taken by Agency/ Outstanding Issues
		recognized Indian tribe (code "E")," add the phrase, "including an Alaska Native Claims Settlement Act (ANCSA) Corporation Shareholder (regional or village)."  5. Instructions for Individuals with Exemption E: Individuals who have Exemption E do not have to pay attention to any of the other instructions; IRS should indicate this on the first page of the instructions to prevent these individuals	5. <b>NO</b>	5. <b>NO</b>	5. Instructions for Individuals with Exemption E: Not accepted. IRS did not address this issue in the final form.
		from wasting time trying to figure out the rest of the complicated instructions.  6. Instructions for Missing Exemption Certificate Number (ECN): On page 7, under specific instructions, Part 1, Column C, it states, "If you were granted a coverage exemption from the Marketplace, but did not receive an ECN, or do not know your ECN, contact the Marketplace to obtain the ECN"; IRS should change this statement to read, "If you applied for an ECN and did not	6. <b>NO</b>	6. YES	6. Instructions for Missing Exemption Certificate Number (ECN): Accepted in part. In Form 8965, IRS finalized this statement as proposed, adding the subsequent statement, "If the Marketplace has not processed your application before you file, enter 'pending.'"
		receive one, skip Part I and use Part III of this form," as Call Center employees do not have this information and the contractor who approves exemptions does not have a published telephone number.  7. List of Tribes: IRS has included in the instructions a list of Tribes that includes Alaska Native Villages; however, the agency should add to the list the names of village and regional corporations formed under ANCSA consistent with the list provided at <a href="http://dnr.alaska.gov/mlw/trails/17b/corpinde">http://dnr.alaska.gov/mlw/trails/17b/corpinde</a>	7. YES	7. N/A	7. <b>List of Tribes</b> : Accepted. IRS addressed this issue as recommended.

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		<u>x.cfm</u> .			
Summary of Benefits and Coverage and Uniform Glossary	31.pp./ TD 9764 DoL RIN 1210-AB69 CMS-9938-F	1. Review of Summary of Benefits and Coverage (SBC) Template: The SBC template might require some modifications as qualified health plan (QHP) issuers work to incorporate the required plan information for the two Indian-specific cost-sharing variations; CMS should review the SBC template to determine any need for modifications to accommodate the information necessary for the "limited" and "zero" cost-sharing variations and engage with tribal representatives on this review.	1. NO	1. NO	Review of Summary of Benefits and Coverage (SBC) Template: Not accepted. The agencies did not address this issue.
		2. Review of SBCs for Accuracy: In the past, tribal representatives have found inaccuracies in some of the SBCs voluntarily prepared by some QHP issuers to describe the Indian-specific cost-sharing variations; CMS should review SBCs to assess the accuracy of the application of the "limited" and "zero" cost-sharing variations.	2. <b>NO</b>	2. <b>NO</b>	Review of SBCs for Accuracy: Not accepted. The agencies did not address this issue.
		3. Sample Language: To address confusion on the part of some QHP issuers, CMS should provide sample language, for use by issuers in the preparation of SBCs, to describe how the "zero" and "limited" cost-sharing variations impact deductibles, co-insurance, etc. for in-network and out-of-network providers.	3. <b>NO</b>	3. <b>NO</b>	3. Sample Language: Not accepted. The agencies did not address this issue.



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Tribal Consultation Policy	64.c./ Treasury (no reference number)	Employer Shared Responsibility Requirement: Under the current IRS interpretation of the employer shared responsibility requirement under ACA, tribal employers would have to incur the costs of purchasing health coverage for their member employees or pay a penalty for not offering them coverage—in either case requiring them to pay for coverage for many tribal members only because they work for the Tribe—but this interpretation does not comport with congressional intent, the federal trust responsibility, or CCIIO policies encouraging Tribes to enroll their members in the Marketplace without regard to the fact that an offer of coverage by a tribal employer would disqualify them from available subsidies; IRS should revise its Interim Tribal Consultation Policy to ensure active consultation with Tribes to address this and other issues as the agency interfaces with other federal agencies responsible for implementing ACA.	NO	NO	Employer Shared Responsibility Requirement: Not accepted. Treasury did not address this issue.
Additional Requirements for Charitable Hospitals	66.c./ TD 9708 (REG- 130266-11 and REG-106499- 12)	Hospitals Operated by Tribes: The proposed rule (REG-130266-11, see 66.a.) should expressly clarify that hospitals operated by tribes or tribal organizations, even as part of a 501(c)(3) organization, are exempt from its application to avoid ambiguity on this issue.	YES	N/A	Hospitals Operated by Tribes: Accepted. IRS did not address this recommendation in TD 9708 but accepted it previously. In the preamble to REG-106499-12 (see 66.b.), IRS clarified that, "pending any future guidance regarding other categories of hospital organizations or facilities,

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	See also 66.a. and 66.b.	Based on its definitions of "hospital facility" and "hospital organization," the rule applies solely to entities recognized or seeking recognition as tax exempt under 26 U.S.C. § 501(c)(3) that operate a facility required by a state have a license, registration, or similar recognition as a hospital. No states have asserted their authority to require a license of a tribal hospital facility, and the Indian Self-Determination and Education Assistance Act of 1975 and subsequent amendments, as well as the Indian Health Care Improvement Act, pre-empt any state authority in this area.			a tribal facility that is not required by a state to be licensed, registered, or similarly recognized as a hospital is not a 'hospital facility' for purposes of section 501(r), and a section 501(c)(3) organization will not be considered a 'hospital organization' solely as a result of operating such a tribal facility." [78 FR 20525]
Notice of Benefit and Payment Parameters for 2016	89.h./ CMS-9944-F	1. Requirement on Summary of Benefits and Coverage (SBC): The proposed rule would establish a requirement that QHP issuers prepare an SBC for each plan variation, such as the "zero cost-sharing variation" and the "limited cost-sharing variation"; in regard to this requirement, CMS should:   • a. Retention: Retain this requirement, as to date, information on Indian-specific cost-sharing protections provided by issuers to consumers, if any, often proves confusing or incorrect, prompting some Al/ANs to decide not to enroll in coverage through a Marketplace;	1. a. YES	1. a. N/A	Requirement on Summary of Benefits and Coverage (SBC):      a. Retention: Accepted. CMS addressed this issue as recommended.



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		b. Encouraging Issuer Compliance:     Encourage issuers to prepare SBCs for use during the 2015 benefit year but no later than the first day of the Marketplace open enrollment period for the 2016 benefit year;	1. b. <b>NO</b>	1. b. YES	b. Encouraging Issuer Compliance:     Accepted in part. CMS approved the requirement that QHP issuers provide SBCs for plan variations no later than the first day of the next Marketplace open enrollment period for the individual market for the 2016 benefit year, specifying this date as November 1, 2015.
		<ul> <li>c. Regulatory Cross-Reference: Add a cross-reference to the requirement to prepare an SBC in the regulation on SBCs (45 § 147.200) by inserting in §147.200 the following language (in brackets and bold):         "§147.200 Summary of benefits and coverage and uniform glossary. (a) Summary of benefits and coverage(1) In general. A group health plan (and its administrator as defined in section 3(16)(A) of ERISA), and a health insurance issuer offering group or individual health insurance coverage, is required to provide a written summary of benefits and coverage (SBC) for [each plan variation of] each benefit package [, as indicated in §156.420(h)] without charge to entities and individuals described in this paragraph (a)(1) in accordance with the rules of this section"; and</li> <li>d. Examples Regarding Compliance: In the preamble to the final rule, and in</li> </ul>	1. c. NO  1. d. NO	1. c. NO  1. d. NO	<ul> <li>c. Regulatory Cross-Reference: Not accepted. CMS did not address this issue.</li> <li>d. Examples Regarding Compliance: Not accepted. CMS did not address</li> </ul>



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		subsequent guidance documents, provide examples of when QHP issuers must provide SBCs to comply with the requirements set forth in § 147.200 and § 156.420(h) and the circumstances, if any, under which a single SBC can satisfy the requirement for multiple plans.			this issue.
		2. Hardship Exemption: The proposed rule includes a provision that would codify the newly established process for obtaining the hardship exemption from the tax penalty for IHS-eligible individuals; in regard to this provision, CMS should:			2. Hardship Exemption:
		a. Retention: Retain this provision (§ 155.605(g)(6)(iii)), which would make agency regulations consistent with revised IRS regulations; and	2. a. YES	2. a. N/A	a. Retention: Accepted. CMS addressed this issue as recommended.
		b. Paper-Based Application Process: Refocus attention on fixing the paper-based exemption application process through Federally-Facilitated Marketplaces by allocating sufficient resources and making the current status of individual applicationsas well as applications in the aggregate-more transparent.	2. b. <b>NO</b>	2. b. YES	b. Paper-Based Application Process:     Not accepted. CMS did not address     this issue specifically but stated in     CMS-9944-F, "We remain committed to     improving the Exchange exemptions     process."
		Code Citation to Definition of Indian     Under Medicaid: The proposed rule	3. YES	3. N/A	3. Code Citation to Definition of Indian Under Medicaid: Accepted. CMS



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		includes a provision that would amend § 155.605(g)(6)(i) by changing the citation to 42 § 447.50 to 42 § 447.51, which cross- references the definition of Indian used for Medicaid purposes; CMS should retain this provision.  4. Network Adequacy and Essential Community Provider Provisions: The proposed rule would codify some of the network adequacy and essential community provider (ECP) provisions that appear in the CCIIO 2015 Issuer Letter and apply solely under the FFM, including 1) codifying the requirement that QHP issuers offer contracts to all Indian health care providers (IHCPs), 2) requiring/encouraging "good faith" offers pertaining to payment rates, 3) adding a requirement that QHP-IHCP contracts apply the special terms and conditions under Federal law pertaining to IHCPs (contained in the QHP Addendum), and 4) applying the requirement that QHP issuers offer contracts to IHCPs: in regard			A. Network Adequacy and Essential Community Provider Provisions:
		<ul> <li>issuers offer contracts to IHCPs; in regard to these provisions, CMS should:</li> <li>a. Mandatory Offer: Retain the requirement that QHP issuers offer contracts to all IHCPs in the QHP service area;</li> <li>b. 30 Percent ECP Standard: At a minimum, maintain the minimum standard of contracting with at least 30</li> </ul>	<ol> <li>a. YES</li> <li>b. YES</li> </ol>	4. a. N/A 4. b. N/A	<ul> <li>a. Mandatory Offer: Accepted. CMS addressed this issue as recommended.</li> <li>b. 30 Percent ECP Standard: Accepted. CMS addressed this issue as recommended.</li> </ul>



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		percent of available ECPs until such time as quantitative evidence indicates that enrollees have reasonable and timely access to health care services;			
		c. "Good Faith" Contract Offers:     Retain the provision requiring "good faith" contract offers to IHCPs, but 1) clarify that the minimum payment rate provision exists as a requirement rather than an "expectation" and 2) include the minimum payment rate requirement in the final regulations, rather than limiting it to the preamble;	4. c. <b>NO</b>	4. c. YES	c. "Good Faith" Contract Offers:     Accepted in part. CMS retained this provision and stated in CMS-9944-F,     "We do not intend to prescribe such specificity regarding contract negotiations between parties.     Therefore, we are not requiring a minimum payment rate provision, and instead reiterate our expectation that QHP issuers offer contracts in good faith." In addition, CMS codified the inclusion of IHCPs in the definition of ECP to "emphasize that these providers are among the ECP groups to which issuers must extend contract offers in good faith to satisfy §156.235(a)."
		d. QHP Addendum Language: Modify the language referencing the QHP Addendum to make it consistent with the wording of the CCIIO 2015 Issuer	4. d. <b>NO</b>	4. d. YES	<ul> <li>d. QHP Addendum Language: CMS did not address this issue. According to CMS in CMS-9944-F, "We believe the requirement that issuers apply the</li> </ul>



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		Letter, as the proposed rule appears to require application of the Indian- specific provisions in Federal law but not (as required in the CCIIO 2015 Issuer Letter) actual use of the Addendum;			special terms and conditions necessitated by Federal law and regulations as referenced in the recommended model QHP addendum, along with encouraging issuer use of the recommended model QHP addendum in guidance, strikes the desirable balance between allowing the minimal flexibility that issuers have requested while ensuring inclusion of the fundamental provisions of the model QHP addendum within the issuer contractual offers to the Indian health providers. Therefore, while we strongly encourage issuers to use the model QHP Addendum, we are not requiring that they do so."
		<ul> <li>e. "Alternative Standard" for Issuers: Strengthen the "alternative standard" for QHP issuers to comply with ACA requirements by 1) adding a requirement that they indicate efforts taken to date to meet the ECP standard and 2) making publicly available their narrative description of efforts taken to date, as well as their plan on "how the plan's provider network will be strengthened toward satisfaction of the ECP standard prior to the start of the benefit year"; and</li> <li>f. State-Based Marketplace (SBM) Standards: Add language to the preamble of the final rule "urging"</li> </ul>	4. f. YES	4. f. N/A	<ul> <li>e. "Alternate Standard" for Issuers:         Not accepted. CMS did not address         this issue.</li> <li>f. State-Based Marketplace (SBM)         Standards: Accepted. CMS         addressed this issue as recommended.</li> </ul>



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		SBMs to apply the IHCP contracting standards to QHPs offered through SBMs.			
		5. Application of Cost-Sharing Protections for Al/AN Families: Responses from CMS to earlier comments from tribal organizations indicated a willingness to address problems with the application of cost-sharing protections for families with Al/AN and non-Al/AN members beginning with the 2016 benefit year, but the proposed rule does not address this issue; in regard to this concern, CMS should 1) implement tribal recommendations (made on CMS-9964-P in December 2012) to eliminate the potential for an increase in the aggregate premiums and to prevent shifting of out-of-pocket (OOP) liabilities to non-Indian family members or 2) provide as an administrative convenience the ability of other IHS-eligible family members to enroll in the same zero cost-sharing variation or limited cost-sharing variation in which Indian members of the	5. <b>NO</b>	5. NO	<ol> <li>Application of Cost-Sharing Protections for Al/AN Families: Not accepted. CMS did not address this issue.</li> </ol>
		family qualify.  6. Al/AN Family Tag-Along Policy: At the request of tribal organizations, CCIIO issued guidance to enrollment assisters on November 15, 2014, indicating that family members of individuals eligible for the Monthly Special Enrollment Period (SEP) for Indians can enroll in Marketplace coverage with the eligible individuals, and although the proposed rule would make	6. <b>NO</b>	6. YES	6. Al/AN Family Tag-Along Policy: Not accepted. In CMS-9944-F, CMS stated, "An Indian as provided under section 4(d) of the Indian Self Determination and Education Assistance Act (ISDEAA) and section 4 of the Indian Health Care Improvement Act (IHCIA) is defined as an individual who is a member of an Indian tribe. Both ISDEAA and IHCIA have nearly identical language

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		several modifications to SEP regulations (§155.420), it would not codify this provision; in regard to this provision, CMS should add this provision to the final rule by inserting in §155.420(d)(8) the following language (in bold): "(8) The qualified individual who is an Indian, as defined by section 4 of the Indian Health Care Improvement Act, or his or her dependent, may enroll in a QHP or change from one QHP to another one time per month."  7. Maximum Out-of-Pocket Costs for Individuals: The proposed rule includes language clarifying (for the 2016 benefit year and beyond) that the annual limitation on cost-sharing for self-only coverage applies to all individuals, regardless of whether the individual is covered by a self-only plan or a family plan, with the limit let at \$6,850 in 2016; CMS should retain this provision.	7. YES	7. YES	that refers to a number of Indian entities that are included in this definition on the basis that they are recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians. As such, the statute specifically provides the special enrollment period defined in paragraph (d)(8) of this section as applying to the individual who is eligible for special programs and services because of their status as an Indian, and not their dependents."  7. Maximum Out-of-Pocket Costs for Individuals: Accepted. CMS addressed this issue as recommended.
Eligibility Determinations for Indian-Specific CSRs	89.k./ TTAG (no reference number)	Eligibility: CCIIO should—     Audit the eligibility determination algorithm used by the Federally-Facilitated Marketplace (FFM) to confirm implementation of the eligibility determinations for the two Indian-specific cost-sharing variations (CSVs) in the application computer program	1. NO	1. YES	1. Eligibility: Accepted in part. According to CCIIO, "although the limited cost-sharing plan variation is sometimes described as one suitable for Indians with household incomes greater than 300 percent of the FPL, enrollment in the limited cost-sharing plan variation is generally available to Indians of any income, including those with household incomes below 100 percent of

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		<ul> <li>and the determination process according to federal regulations and discuss the findings with TTAG.</li> <li>Indicate on the FFM determination letters the specific cost-sharing variation for which an Indian applicant has qualified (the "02" or "03" CSV) and provide a summary description of the relevant Indian-specific CSV.</li> </ul>			the FPL and above 400 percent of the FPL, who are not eligible for premium tax credits." CCIIO added, "Thus, the Marketplaces do not require a financial eligibility determination for Indian applicants for the limited cost-sharing plan variation under 45 CFR 155.350(b), the <i>Special cost-sharing rule for Indians regardless of income</i> . The Marketplaces automatically enroll American Indians and Alaska Natives applicants who do not request an eligibility determination into limited cost-sharing plan variations, as required under this regulation."
		<ul> <li>General Protections: CCIIO should—         <ul> <li>Increase education of qualified health plan (QHP) issuers on Indian-specific cost-sharing protections by:</li> <li>Providing language on the Indian-specific CSVs for inclusion in QHP Summary of Benefits and Coverage documents due by October 2015.</li> <li>Requiring issuers to indicate on their insurance cards the type of CSV applicable to the enrollee.</li> </ul> </li> <li>Communicate the availability of the Health Insurance Complaint System (HICS) and permit tribal sponsors of enrollees to submit multiple (repeat)</li> </ul>	2. <b>NO</b>	2. NO	General Protections: Not accepted. CCIIO did not address this issue.



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		cases involving a single QHP but multiple QHP enrollees in one HICS submission.  • Ensure QHP issuers apply the Indian-specific CSVs correctly, drawing upon filings through HICS to identify erroneous application of Indian-specific CSVs, and prioritize conducting broader audits of the application of Indian-specific CSVs.			
		<ul> <li>Payments to Indian Health Care Providers: CCIIO should—         <ul> <li>Ensure QHP issuers make full payments to Indian health care providers, without deducting waived cost-sharing amounts.</li> <li>Communicate availability of HICS and permit providers to submit multiple (repeat) cases involving a single QHP in one submission.</li> </ul> </li> </ul>	3. NO	3. NO	3. Payments to Indian Health Care Providers: Not accepted. CCIIO did not address this issue.
		4. Shorthand Descriptions of Indian- Specific CSVs: CCIIO should consider adopting one or more of the following abbreviated descriptions for use by CMS when it requires a shorthand version of the explanation of the Indian-specific CSV—  OPTION 1:  00 - Non-Exchange variant	4. NO	4. NO	<ol> <li>Shorthand Descriptions of Indian- Specific CSVs: Not accepted. CCIIO did not address this issue.</li> </ol>



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		<ul> <li>01 - Exchange variant (no CSR)</li> <li>02 - Open to Indians between 100% and 300% FPL</li> <li>03 - Open to Indians of any income level, or income not determined</li> <li>04 - 73% AV Level Silver Plan CSR</li> <li>05 - 87% AV Level Silver Plan CSR</li> <li>06 - 94% AV Level Silver Plan CSR"</li> <li>OPTION 2:</li> <li>"02" or "Zero cost-sharing variation" protections are available to persons who meet the ACA's definition of Indian, have household income between 100 and 300 percent FPL, are eligible for premium tax credits, and enroll in coverage through a Marketplace.</li> <li>"03" or "Limited cost-sharing variation" protections are available to persons who meet the ACA's definition of Indian, have any household income level, and enroll in coverage through a Marketplace.</li> </ul>			
		<ul> <li>Persons eligible for the limited cost-sharing variation do not have to be eligible for premium tax credits and can decide to not request an</li> </ul>			



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		eligibility determination for insurance affordability programs ( <i>e.g.</i> , premium tax credits).			
		• OPTION 3:			
		<ul> <li>"Zero cost-sharing variation"         ("02")         Protections available to persons enrolled in coverage through a Marketplace who:         <ul> <li>Meet the ACA's definition of Indian</li> <li>Have household income between 100 and 300 percent FPL</li> <li>Qualify for premium tax credits</li> </ul> </li> </ul>			
		<ul> <li>"Limited cost-sharing variation"         ("03")         Protections available to persons         enrolled in coverage through a         Marketplace who:</li> </ul>			
		<ul> <li>Meet the ACA's definition of Indian</li> <li>Have household income of any level</li> <li>Do or do not qualify for premium tax credits</li> </ul>			



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		To receive the "02" or "03" protections, an individual cannot be enrolled in a family plan with individuals who are not eligible for the "02" or "03" protections.			
Enrollee Satisfaction Survey Data Collection	168./ CMS-10488	<ol> <li>Questions Specific to Al/ANs—         Marketplace Survey: To address         questions specific to the experiences of         Al/ANs, CMS should include a section titled         "American Indians and Alaska Natives and         Other Individuals Eligible to Receive         Services from an Indian Health Care         Provider," which should solicit responses to         the below questions.</li> <li>a. Whether the Marketplace provides         specific information on how it         determines "Indian" status for both         Medicaid and QHPs, as well as the         process by which an individual can         challenge an unfavorable         determination;</li> <li>b. What types of documents that the         Marketplace accepts as proof of Al/AN         status, as well as the ease of uploading         or otherwise providing these         documents;</li> <li>c. Whether the Marketplace informs         Al/ANs of their eligibility for a special</li> </ol>	1. N/A	1. N/A	Questions Specific to Al/ANs—     Marketplace Survey: CMS did not include     a revised version of the Marketplace Survey     in this PRA request.



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		<ul> <li>d. Whether the Marketplace explains         (1) the existence of Al/AN-specific         cost-sharing protections under both         QHPs and Medicaid; (2) the         differences in eligibility for cost-sharing         protections in QHPs compared with         Medicaid; and (3) the manner in which         an Al/AN can establish eligibility for         any relevant cost-sharing protection;         <ul> <li>e. Whether the Marketplace specifically                 explains (1) how Al/ANs and IHS-                 eligibles can apply for exemptions from                 the shared responsibility payment; the                differences in the exemption process                 for members of federally recognized                 Indian tribes and shareholders in                 Alaska Native Regional or Village                  Corporations as compared to IHS-                      eligibles; and (3) the actual process for                      obtaining the exemptions; and</li></ul></li></ul>			2. Questions Specific to Al/ANs—QHP Survey:



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		include a section titled "American Indians and Alaska Natives and Other Individuals Eligible to Receive Services from an Indian Health Care Provider," which should solicit responses to the below questions.			
		<ul> <li>a. How the QHP interacts with both the individual Al/AN and health care providers to ensure that Al/ANs do not have cost-sharing for which ACA exempts them;</li> </ul>	2. a. <b>NO</b>	2. a. <b>NO</b>	a. Not accepted. CMS did not address this issue.
		b. Whether the individual AI/AN has ever had cost-sharing (as defined) in any circumstances in which ACA exempts then and, if so, how the individual resolved the dispute with the QHP, as well as the availability of resources in the event of an unresolved dispute;	2. b. <b>NO</b>	2. b. <b>NO</b>	b. Not accepted. CMS did not address this issue.
		<ul> <li>c. Whether the QHP includes the I/T/U of the individual AI/AN within its network;</li> </ul>	2. c. <b>NO</b>	2. c. <b>NO</b>	c. Not accepted. CMS did not address this issue.
		<ul> <li>d. Whether and why the QHP ever refused to pay a bill, in full or in part, for services provided at an I/T/U; and</li> </ul>	2. d. <b>NO</b>	2. d. <b>NO</b>	d. Not accepted. CMS did not address this issue.
		e. What interaction the Al/AN individual has experienced with QHP personnel concerning Al/AN-specific issues.	2. e. <b>NO</b>	2. e. <b>NO</b>	e. Not accepted. CMS did not address this issue.



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		3. Al/AN Survey Responses: To address concerns about an inadequate survey response rate from Al/ANs, CMS should designate a portion of the annual funding for the Marketplace and QHP surveys for grants or contracts to tribes, tribal organizations, and/or I/T/Us to conduct the data collection in person in Al/AN communities.	3. N/A	3. N/A	3. Al/AN Survey Responses: Unable to determine whether CMS addressed this issue.
		4. Question Wording and Answers: To ensure accuracy and cultural propriety in the Al/AN context, CMS should change slightly the wording and answers on the below questions.			4. Question Wording and Answers:
		a. Race Questions: Question 77 in the Marketplace survey and Question 94 in the QHP survey ask respondents about their "race," with "American Indian or Alaska Native" included as one option, but Indian status does not constitute a "race" under the law; CMS should use the following set of questions to address this issue:	4. a. <b>NO</b>	4. a. <b>NO</b>	a. Not accepted. CMS did not address this issue.
		"Question 1: Please indicate all of the following that apply to you:			
		<ul> <li>a. American Indian or Alaskan         Native. I am a person having origins in any of the original peoples of North,         Central, or South America.     </li> </ul>			



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		b. Asian. I am a person having origins in any of the countries of Asia. c. Black. I am a person having origins in any of the black racial groups of Africa. d. Pacific Islander or Native Hawaiian. I am a person having origins in Hawaii, the Philippines, or other Pacific Island. e. White. I am a person having origins in any of the original peoples of Europe, North Africa, or the Middle East.  [For those who check 'a. Al/AN,' regardless of any other race or ethnicity they check, CMS should ask:]  Question 2a: Are you a member of a federally recognized Indian tribe or a shareholder in an Alaska Native Regional or Village Corporation?  a. Yes b. No c. Don't Know  Question 2b: Have you ever obtained health services from an Indian Health Service, tribal, or urban Indian health program, or are you eligible to do so? a. Yes			



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		<ul> <li>b. Recent Provider Visit Questions:         <ul> <li>In the section of questions (3-9) in the QHP survey about whether an individual went to a "clinic, emergency room, or doctor's office" in the past several months, add "Indian health facility" as a possible response.</li> </ul> </li> <li>c. "Personal Doctor" Questions: In the section of questions in the QHP survey (21-38) about having a "personal doctor," change this term to "regular source of health care," as in most I/T/U facilities, individuals might see various providers, including doctors, nurse practitioners, physician assistants, and community health aides.</li> </ul>	4. b. NO 4. c. NO	4. b. NO 4. c. NO	<ul> <li>b. Not accepted. CMS did not address this issue.</li> <li>c. Not accepted. CMS did not address this issue.</li> </ul>
FEHBP: Eligibility for Temporary and Seasonal Employees	174.c./ OPM (RIN 3206-AM86)	1. Availability of Waiver for Tribes: The proposed rule would require FEHBP-participating employers, including Tribes, to offer FEHBP plans to a newly eligible group of temporary, intermittent, and seasonal employees but would grant the OPM Director the discretion to waive this extension for certain employers that demonstrates a waiver is "necessary to avoid an adverse impact on the employer's	1. YES	1. N/A	Availability of Waiver for Tribes:     Accepted. OPM addressed this issue as recommended.

NIHB Evaluation: Impact on Regulations from Tribal Involvement

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Issue	Related RRIAR Ref. #/ File Code	Summary of Tribal Entity Recommendations	Addressed Issue as Recommended	Acknowledged Issue and/or Addressed by Other Means	Action Taken by Agency/ Outstanding Issues
		need for self-governance". We do not believe that the opt-out should remain at the discretion of the OPM Director in the Tribal context. OPM should make the waiver available to Tribeswhich, as governments first and employers second, have the best understanding of their governmental, employment, and financial needsupon written request and without preconditions by making the following changes to proposed 5 C.F.R. § 890.102(k):			
		<ul> <li>(k) The Director, upon written request of an employer of employees other than those covered by 5 U.S.C. 8901(1)(A), shall may, in his or her sole discretion, waive application of paragraph (j) of this section to its employees when the employer demonstrates to the Director that the waiver is necessary to avoid an adverse impact on the employer's need for self governance.</li> <li>2. Application of "Common Law" Employee Standard to Tribes: OPM has stated that Tribes participating in FEHBP must offer FEHBP coverage to all of their</li> </ul>	2. YES	2. N/A	2. Application of "Common Law" Employee Standard to Tribes: Accepted. In the final rule, OPM stated, "Several tribal organizations also requested that OPM



Issue	Related RRIAR Ref. #/ File Code	Summary of Tribal Entity Recommendations	Addressed Issue as Recommended	Acknowledged Issue and/or Addressed by Other Means	Action Taken by Agency/ Outstanding Issues	
		<ul> <li>"common law" employees, as defined by IRS, and cannot "offer alternative major medical coverage to employees eligible for FEHB," further noting that the common law determination "does not make distinctions between commercial or governmental functions," a standard that poses difficulty to Tribes, which offer differing forms and levels of health coverage to employees of different tribal agencies and businesses, and deters them from participating in FEHBP; OPM should clarify, in either regulation or guidance, that:</li> <li>Tribes have the discretion to make a good faith determination as to whether an employee or category of employees; and</li> <li>Tribes can offer FEHBP-eligible employees alternative coverage on an entity-by-entity basis.</li> </ul>			clarify the application of the common law employee standard to tribal employers. This common law employee standard is used to determine which employees of tribal employers may be eligible to enroll in FEHB. The proposed rule was limited to a modification of FEHB eligibility for certain temporary, seasonal, and intermittent employees and thus this clarification is outside the scope of this rule." [79 FR 62326] However, in subsequent guidance, OPM indicated that, of as November 20, 2014, tribal employers can enroll employees from all, or fewer than all, of their business units in FEHBP (see 174.d.).	
MEDICARE/MEDICAID ISSUES						
Medicaid DSH and Definition of Uninsured	46.a./ CMS-2315-F	Tribal Consultation: CMS did not engage in tribal consultation on the proposed rule as required; CMS should engage in consultation with AI/ANs prior to issuing the final rule.	1. <b>NO</b>	1. <b>NO</b>	Tribal Consultation: Not accepted. CMS did not address this issue.	
		Treatment of IHS and Tribal Hospitals:     When IHS and tribal hospitals render services to IHS-eligible individuals,	2. <b>NO</b>	2. YES	2. Treatment of IHS and Tribal Hospitals: Not accepted. In CMS-2315-F, CMS stated, "The determining factor in deciding whether	



Issue	Related RRIAR Ref. #/ File Code	Summary of Tribal Entity Recommendations	Addressed Issue as Recommended	Acknowledged Issue and/or Addressed by Other Means	Action Taken by Agency/ Outstanding Issues
		compensation for these services is assumed, despite the acknowledged inadequacy of available IHS funding, and these hospitals cannot include the cost of delivering these services to otherwise uninsured individuals in their calculation of uncompensated care, meaning that the proposed rule would effectively exclude them from participation in the Medicaid DSH program; CMS should address this issue in the final rule, possibly by extending to IHS and tribal hospitals the regulatory protections under the Medicaid DSH program for facilities that receive funding from a State or local government.			an American Indian or Alaska Native has health insurance for an inpatient or outpatient hospital service is if the providing entity is an IHS facility or tribal health program. In the case of contract services, the coverage of the services is specifically authorized via a purchase order or equivalent document because individuals in these circumstances are considered to have a source of third party payment. The cost of services and any revenues received would be excluded from the DSH calculation. Individuals obtaining inpatient or outpatient hospital services from a non-IHS or tribal facility without a purchase order (or other authorization) would be considered uninsured for these services. The costs of these services and revenues received could be included in the DSH limit calculation." [79 FR 71689]  In addition, CMS stated, "An American Indian or Alaska Native would be considered to have no health insurance when he or she obtains services without a purchase order or equivalent authorization to pay for them. If contract providers have provided needed services that were not pursuant to a purchase order, the American Indian or Alaska Native would be considered uninsured (absent private coverage) and the costs and any revenues associated with these services could be included in the limit." [79 FR 71689-90]



Issue	Related RRIAR Ref. #/ File Code	Summary of Tribal Entity Recommendations	Addressed Issue as Recommended	Acknowledged Issue and/or Addressed by Other Means	Action Taken by Agency/ Outstanding Issues
		3. Use of HIPAA Definition of Creditable Coverage: The proposed rule uses the HIPAA definition of creditable coverage; CMS should not use this definition, which is neither required nor, in the case of services rendered to IHS-eligible individuals, warranted, as it results in considering IHPs rendering services to IHS-eligible persons as fully compensated for these services without regard to the level of available IHS funding.	3. NO	3. YES	CMS also noted that the recommendation to treat IHS and tribal hospitals similarly to "a State or unit of local government within a State" falls outside the scope of the rule. [79 FR 71690]  3. Use of HIPAA Definition of Creditable Coverage: Accepted in part. According to CMS in CMS-2315-F, "In this final rule, we are defining "individuals who have no health insurance (or other source of third party coverage) for the services furnished during the year" for purposes of calculating the hospital-specific DSH limit on a service-specific basis, rather than on an individual basis, and thus do not make reference to the regulatory definition of creditable coverage. The definition instead requires a determination of whether, for each specific service furnished during the year, the individual has third party coverage." [79 FR 71690]
OTHER ISSUES					

# Attachment 5: Tribal Recommendations with Agency Response Indicating Potential **Future Action**

Attachment 5 lists tribal recommendations on which the agency, in its response, indicated the potential for future action (in some form). Section A includes recommendations on which the agency acted during FY 2015. Section B includes recommendation on which the agency, sometime between October 1, 2012, and September 30, 2014, indicated in its response the potential for future action (but no action has yet been taken).

#### A. Regulations Acted Upon in FY 2015

### ECP Data Collection to Support QHP Certification for PY 2017 (CMS-10571)

#### 1. Recommendation

Window to Update HHS ECP List: As indicated by CCIIO representatives, between October 23, 2015, and November 23, 2015, CMS plans to open the Essential Community Providers Provider Petition for the 2017 Benefit Year (Petition) for providers to make corrections and updates to their entries on the HHS ECP List, but this one-month window might not allow sufficient time for the hundreds of non-IHS Indian health care providers (ICHPs) to access and update their information through the Petition; CMS should:

- Consider extending the timeframe for making updates to the HHS ECP List;
- Prior to excluding current IHCPs on the HHS ECP List, undertake proactive efforts to contact individual providers to inform them of the need to update their entry or entries on the HHS ECP List;
- Prior to excluding current IHCPs on the HHS ECP List, provide a list of the IHCPs that have failed to update their entry or entries to the Tribal Self-Governance Advisory Committee to IHS, the TTAG, and/or IHS to allow proactive outreach by these organizations; and/or
- Provide a six-month grace period after the November 23, 2015, deadline prior to removing any IHCPs from the HHS ECP List.

#### Agency Response

Accepted in part. In a subsequent PRA notice, CMS stated that it will consider the request for a grace period or a transition year prior to removing otherwise qualified providers from the HHS ECP List.

#### B. Regulations Acted Upon Prior to FY 2015 (Since October 1, 2012)

Program Integrity; Amendments to the HHS Notice of Benefit and Payment Parameters (CMS-9957-F2, CMS-9964-F3)

### 1. Recommendation

**Data Collection**: To evaluate the operation of the program, CMS should ensure the collection of a robust amount of data on the actual payments made by issuers under the Indian-specific cost-sharing variations and ensure the collection of data is representative of the experiences of all health plans, with consideration to factors such as the service areas of plans, the degree of I/T/U penetration in the service areas, the percentage of Al/ANs enrolled in a plan, plan size and market concentration, and whether plans provided protections under the limited or zero costsharing variations.

### Agency Response

Accepted in part. In the final rule, CMS did not directly address collection of data on Indianspecific cost-sharing variations but clarified the standards for reporting information on the effective cost-sharing parameters. Specifically, CMS specified that a QHP issuer using the simplified methodology must submit to HHS, in the manner and timeframe established by HHS, the effective cost-sharing parameters for each standard plan offered by the QHP issuer in the individual market through the Exchange for each set of circumstances outlined in this final rule. CMS also indicated plans to provide future guidance on the manner and timeframe of this submission, and this issuance might provide an opportunity for further comment on this issue.

### 2. Recommendation

Primary Payment Methodology: CMS should continue to use as the primary payment methodology a mechanism based on actual (and not estimated) payments made by issuers for the cost-sharing protections provided to Al/ANs under the limited and zero cost-sharing variations and propose to transition to an alternative payment mechanism only after demonstrating such an alternative would not create counter-productive financial incentives.

### Agency Response

Accepted in part. The final rule requires all QHP issuers to use the standard methodology. which relies on actual cost-sharing reduction payments, after 2016. However, CMS stated that it will continue to consider alternative approaches for reimbursing QHP issuers, including a capitated payment system, indicating that this issue will remain a concern in the future.

# 2015 Letter to Issuers (Letter) in FFMs (CCIIO/no reference number)

#### 3. Recommendation

QHP Coverage of Primary Care: CMS should require issuers (through a rule) to make available plans allowing three primary care office visits before the patient must meet any deductible.

### Agency Response

N/A. CMS did not discuss this issue in the final letter. However, CMS stated, generally: "Some policies with operational implications in the Draft 2015 Letter to Issuers are not being finalized in this Final 2015 Letter to Issuers, with the intent to continue work to accomplish them." This statement indicates a potential willingness by CMS to address this issue in future regulations or guidance.

#### Methodology for Designation of Frontier and Remote Areas (HRSA/no reference number)

#### 4. Recommendation

**Use of 60 Minutes Travel Time from the Central Place**: The proposed methodology would measure travel time by calculating a one-way trip by the fastest paved road route with one-hour travel time added for locations only accessible by air, but this measure fails in a number of ways; HRSA should develop a metric based on added cost in all cases in which transportation by some means other than a personal vehicle is required.

### Agency Response

Accepted in part. **From the Final Methodology**: HRSA recognized that the 60-minute travel time "represents different distances depending on circumstances, such as available roads or highways, and depending on the mode of transportation used, such as cars, boats, or aircraft," but concluded that the "current model addresses concerns stated in regards to remote areas with limited road infrastructure or that are reliant on non-road transport."

HRSA, however, did indicate plans to examine the possibility of creating another level of designation for extremely remote Frontier Areas "that will be 2 or more hours travel time from the nearest Urbanized Area in future versions of the FAR Codes."

#### 5. Recommendation

**Need for Census Tract and County Version**: The proposed methodology would begin at the 1x1 kilometer grid level; HRSA should organize grid data in a database that allows aggregation at a variety of levels (including each town, county, Indian reservation, school district, county, census block, census tract, etc.), with a clear definition of their development.

### Agency Response

Accepted in part. **From the Final Methodology**: HRSA acknowledged the limitations of the use of the 1x1 kilometer grid, stating, "In the revision of the FAR methodology, the use of a 1 x 1 kilometer grid will be replaced with a 1/2 x 1/2 kilometer grid, which will increase accuracy, and further functionality will be added to the Web site allowing users to drill down and examine small areas." HRSA added that "this level of analysis obviates the need to overlay other sources of data, while still allowing users to include other data appropriate to their use of the FAR codes."

In regard to concerns about distances between population centers in Alaska, HRSA said that it plans to examine the issue, "when data from Alaska are added to the FAR codes through use of

the Census 2010 data, to determine whether the use of the grid layer will allow an accurate representation of the Frontier status of the communities that make up the Bethel Census area."

# Standards for Navigators, Non-Navigator Assistance Personnel, and Certified Application Counselors in FFE (CMS-9955-F)

### 6. Recommendation

**Training Standards**: CMS should ensure that strict background checks do not eliminate Al/ANs from serving as Navigators, non-Navigator assistance personnel, and certified application counselors, as many Al/ANs have suffered from drug or alcohol addiction that has led to a criminal record.

#### Agency Response

Not accepted. From **CMS-9955-F**: For Navigators and non-Navigator assistance personnel, CMS indicated that potential exists to address this issue in the development of the federal application process and state requirements.

For certified application counselors, CMS indicated that future HHS regulations on the "processes through which Federally-facilitated Exchanges and State Partnership Exchanges can oversee their activities" might provide an opportunity to address this issue.

Program Integrity: Exchange, SHOP, and Eligibility Appeals (CMS-9957-F)

#### 7. Recommendation

**Employer-Sponsored Coverage Information in Eligibility Determinations**: If an applicant cannot obtain employer-sponsored coverage information as required for conduct an eligibility determination in a QHP or for insurance affordability programs, CMS should:

- If an employee informs an Exchange that he or she has made a good faith attempt to obtain employer-sponsored coverage information from an employer without result, require the Exchange to send a follow-up letter to the employer advising the employer that the employee seeks an insurance affordability determination but cannot receive this determination without this information (this letter should provide the employer with a certain number of days to submit this information to the Exchange); and
- If the employer fails to submit employer-sponsored coverage information to the Exchange within the time frame, require the Exchange to provide the employee with an insurance affordability determination without this information based on the good faith attempts by the employee and the Exchange to obtain this information.

#### Agency Response

Not accepted. CMS did not address this issue as recommended but indicated that future efforts between the agency and the Department of Labor (DoL) to educate employers about making information regarding employer-sponsored coverage they offer available to employees for the purpose of submitting an application for insurance affordability programs in a timely fashion might provide an opportunity to address this issue.

#### Eligibility and Enrollment for Exchanges, Medicaid and CHIP (CMS-2334-F)

#### 8. Recommendation

Essential Health Benefits in Alternative Benefits Plan—Mental Health Benefits: CMS should take any action within its authority to encourage all Alternative Benefit Plans to expand their mental health and substance use disorder benefits.

#### Agency Response

Not accepted. In CMS-2334-F, CMS indicated that potential exists to address this issue with states as they redesign their Medicaid programs.

# 9. Recommendation

Documenting Use of I/T/U Facilities or CHS Referrals to Establish Eligibility For Cost-**Sharing Exemptions**: The American Recovery and Reinvestment Act of 2009 (ARRA) eliminates Medicaid cost sharing for Al/ANs who receive any item or service directly from IHS or an I/T/U or through referral under Contract Health Services (CHS), and CMS proposed to implement this statutory exemption in CMS-2234-P; to determine eligibility for this exemption, CMS should require, whenever feasible, the use of data matching to reduce the burden on individuals and states to obtain paper confirmation, and in cases in which data matching cannot occur, CMS should provide a number of examples of acceptable alternatives for confirmation.

#### Agency Response

Not accepted. In CMS-2334-F, CMS indicated that potential exists to address this issue with states as they establish processes for verifying premiums and cost-sharing exemptions for AI/ANs.

**Exchanges: Minimum Essential Coverage Provisions (CMS-9958-F, TD 9632)** 

#### 10. Recommendation

Electronic Data Matching: CMS and IRS should enter into discussions a) through TTAG and b) through formal tribal consultation to develop an approach to provide electronic data matching with the IHS database as one means of verifying Indian status for purposes of the (requested) exemptions from the tax penalties.

### Agency Response

Not accepted. In CMS-9958-F, CMS appeared open to the possibility of electronic data matching with the IHS database. Tribal entities should seek discussions on this issue and opportunities to address it in future regulations or guidance. In TD 9632, IRS did not address this issue but indicated that potential exists to address it through agency forms, instructions, or other publications.

### Notice of Benefit and Payment Parameters for 2014 (CMS-9964-F)

#### 11. Recommendation

Rule for Families with AI/AN and Non-AI/AN Members: For families with AI/AN and non-AI/AN members, CMS should:

- Calculate the aggregate family premium by calculating the premium for each family member when enrolled in a single family policy at the silver metal level;
- Enroll the family members in two separate plans that may be different in only the family type and the cost-sharing variation, with no change in the aggregate premium paid; and
- Establish the maximum out-of-pocket liability for the "non-Al/AN plan" as a proportion of the maximum liability of a single family plan.

### Agency Response

Not accepted. CMS did not address this issue but indicated that it would reconsider it in future years. In CMS-9964-F, CMS stated, "We will consider adopting the approach recommended by commenters for future benefit years; however, given the current timeframe and operational concerns, we believe that for the 2014 benefit year it is infeasible to require issuers to submit plan variations that take into account cost-sharing obligations for Indian and non-Indian family members covered under a single QHP policy. ... If we propose to change the policy for years beginning in 2016, we will provide issuers with sufficient notice and opportunity to comment to effectuate the required operational change."

### Multi-State Plan Program for Exchanges (OPM35-12-R-0006, OPM RIN 3206-AM47)

#### 12. Recommendation

Phased Expansion: The proposed rule requires that issuers failing to offer statewide coverage propose a plan for expanding coverage and that they cannot determine coverage based on discriminatory factors or designed to avoid high utilization, high cost, or medically underserved populations; OPM should increase the specificity of these requirements to ensure that Al/ANs have access to Multi-State Plans (MSPs).

# Agency Response

Accepted in part. OPM did not make the recommended changes but indicated in the Final Rule (RIN 3206-AM47) that, as it reviews MSPP issuer applications, it will pay special attention to medically underserved service areas, such as rural areas and Al/AN populations.

### 13. Recommendation

Bronze Plan: OPM should require MSPP issuers to offer at least one plan at the bronze level to maximize AI/AN participation.

### Agency Response

Not accepted. OPM did not make the recommended changes but indicated in the Final Rule (RIN 3206-AM47) that it will consider plans that offer catastrophic or bronze levels of coverage when allowed by states.

#### 14. Recommendation

Premiums and Child-Only Plan: OPM should require QHPs and MSPs to adopt provisions to ensure that the total premium paid for the multiple plans potentially required for a family with both AI/AN and non-AI/AN members is no larger than the premium required if the entire family could have enrolled in a single plan.

### Agency Response

Not accepted. OPM indicated in the Final Rule (RIN 3206-AM47) that it lacks the regulatory authority to address this issue but added that, where appropriate, OPM will coordinate closely with HHS on areas of special concern for Al/AN adults and children.

#### 15. Recommendation

Compliance with Applicable State Law: With certain exceptions, MSPP issuers must comply with State law with respect to each of its MSPs; however, OPM should acknowledge that Federal Indian law supersedes state law.

### Agency Response

Accepted in part. OPM did not make the recommended changes but acknowledged in the Final Rule (RIN 3206-AM47) the unique concerns of I/T/Us, including concerns that involve the interaction of State law and Federal Indian law and indicated plans to address these concerns, to the extent practicable, through contractual terms.

#### 16. Recommendation

Contract Performance: OPM should ensure that the related standards address failure by MSPs to properly pay I/T/Us.

### Agency Response

Not accepted. OPM did not make the recommended changes but indicated in the Final Rule (**RIN 3206-AM47**) it will address compliance more specifically in the terms of MSPP contracts.

#### 17. Recommendation

**Tribal Sponsorship**: OPM should establish the rules and conditions that will facilitate Tribal sponsorship of individuals to enroll in MSPs.

### Agency Response

Accepted in part. In the Final Rule (**RIN 3206-AM47**), OPM indicated that it has begun exploring whether potential issuers have the capacity to perform premium aggregation and/or accept aggregated premiums. In the Final Application (**OPM35-12-R-0006**), OPM added language that requires MSPs to "Describe your capacity to accept aggregated premium payments from employers (if proposing SHOP participation) or tribal entities."

#### 18. Recommendation

**Model Indian Addendum**: OPM should require (or establish through regulation equivalent rules) a Model Indian Addendum, regardless of whether CMS decides to only encourage the use of the Addendum.

#### Agency Response

Not accepted. OPM did not make the recommended changes but indicated in the Final Rule (**RIN 3206-AM47**) that it will address this issue in contract negotiations and will continue to coordinate closely with CMS on the use of the standard Indian Addendum by MSPP issuers when contracting with Indian providers.

#### 19. Recommendation

"National" MSPs: OPM should encourage "national" MSPs, as multi-state consistency would help Tribes and tribal organizations that consider purchasing coverage for their members and for Tribes that cross state borders.

#### Agency Response

Accepted in part. OPM did not make the recommended changes but indicated plans to address the issue of reciprocity of coverage among MSPs in States as part of contract negotiations with MSPP issuers and confer with Tribes on this approach and engage them in how MSPP might best meet their needs.