



**PURPOSE:**

The purpose of the Regulation Review and Impact Analysis Report (RRIAR) is to identify and summarize key regulations issued by the Centers for Medicare and Medicaid Services (CMS) pertaining to Medicare, Medicaid, CHIP, and health reform that affect (a) American Indians and Alaska Natives and/or (b) Indian Health Service, Indian Tribes and Tribal organizations, and urban Indian organizations. Furthermore, the RRIAR includes a summary of the regulatory analyses prepared by the National Indian Health Board (NIHB) with the assistance of its partners, and indicates the extent to which the recommendations made by NIHB, Tribal organizations, or the TTAG were incorporated into any subsequent CMS or other Agency actions.

*NOTE: Items associated with a reference number relate to regulations that Tribes, Tribal Organizations, NIHB or TTAG have commented on or with potential implications for Tribal health systems. These can also be found in NIHB's Roster of Pending Regulations.*

**I. Regulations with pending due dates for public comments-**

- 21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program—Comments Due 5/3/2019 (Ref #2)
- Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State-Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers—Comments Due 5/3/2019 (Ref #3)
- Request for Information: Patient Protection and Affordable Care Act; Increasing Consumer Choice through the Sale of Individual Health Insurance Across State Lines Through Health Care Choice Compacts—Comments Due 5/6/2019 (Ref #4)
- Fraud and Abuse: Removal of Safe-Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Managers Service Fees—Comments Due 4/8/2019 (Ref #7)
- Basic Health Program: Federal Funding Methodology for Program Years 2019 and 2020—Comments Due 5/2/2019 (Ref #5)
- Medicaid Program; Covered Outpatient Drug; Line Extension Definition; and Change to the Rebate Calculation for Line Extension Drugs—Comments Due 5/31/2019 (Ref #6)
- Dear Tribal Leader Letter—105(l) leases—Comments Due 4/26/2019

**II. Comments recently submitted by NIHB, TTAG, and/or other Tribal organizations-**

- Comments to FNS: SNAP Able-Bodied Adults without Dependents (ABAWDs) proposed rule—Submitted on 4/2/19 (Ref #8)
- NIHB and NCAI Joint Comments on HHS Tribal Consultation Policy—Submitted on 3/15/2019 (Ref #9)
- National HIV AIDS Strategy and the National Viral Hepatitis Action Plan—Submitted on 3/11/2019 (Ref #10)
- HHS Notice of Benefit and Payment Parameters for 2020—Submitted on 2/19/2019 (Ref#13)
- Comments on Modifying HIPAA Rules to Improve Coordinated Care to the Office for Civil Rights (OCR)—Submitted 2/12/2019 (Ref #11)
- Office of the National Coordinator (ONC) for Health IT Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs—Submitted 1/28/2019 (Ref #1)
- State of Oklahoma request to amend the State's Section 1115(a) "SoonerCare" Choice Program—Submitted 1/18/2019 (Ref #18)
- Health and Human Services (HHS): Healthy People 2030—Submitted 1/17/2019 (Ref #17)
- Medicaid Program; Medicaid and Children's Health Insurance Plan (CHIP) Managed Care—Submitted 1/14/2019 (Ref #19)

- Substance Abuse and Mental Health Services Administration (SAMHSA): State Opioid Response (SOR) and Tribal Opioid Response (TOR) Program Data Collection and Performance Measurement—Submitted 1/9/2019 (Ref #20)
- State of Virginia’s Medicaid Section 1115 Demonstration Application—Submitted 1/6/2019 (Ref #21)
- Comments to CDC: Formative and Summative Evaluation of the National Diabetes Prevention Program—Submitted 12/3/2019 (Ref #22)
- Comments to CDC: Surgeon Generals Call To Action: “Community Health And Prosperity”; Establishment of a Public Docket—Submitted 11/5/2019 (Ref #23)
- Comments to CMS: State of Alabama Medicaid Workforce Initiative Section 1115 Demonstration Application—Submitted 10/21/2018 (Ref #24)
- Healthy Michigan Plan Section 1115 Demonstration Waiver Joint Comments with National Council of Urban Indians (NCUIH)—Submitted on 10/26/2018 (Ref #25)
- Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP—Submitted 10/26/2018 (Ref #26)

Comments submitted by NIHB/MMPC and other organizations can be accessed [HERE](#). Comments submitted by TTAG and other organizations may be accessed [HERE](#).

### III. Regulations under OMB (Office of Management and Budget) review-

- Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020 (CMS-9926-F)—Received at OMB 3/22/2019, pending review (Ref. #13)
- Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3347-P)—Received at OMB 11/8/2018, pending review
- Adoption and Foster Care Analysis and Reporting System (RIN 0970-AC72) —Received at OMB 2/13/2019 , pending review
- Program Integrity Enhancements to the Provider Enrollment Process (CMS-6058-F)—Received at OMB 12/3/2018, pending review
- Methods for Assuring Access to Covered Medicaid Services—Rescission (CMS-2406-P2)—Received at OMB 12/12/2018, pending review
- Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY’2020 Rates (CMS-1716-P)—Received at OMB 1/30/2019, pending review
- FY’2020 Skilled Nursing Facilities (SNFs) Prospective Payment System Rule Update and Quality Reporting Requirements (CMS-1718-P)—Received at OMB 2/27/2019, pending review
- FY’2020 Inpatient Rehabilitation Facility (IRF) Prospective Payment System Rate Update and Quality Reporting Requirements (CMS-1710-P)—Received at OMB 3/1/2019, pending review
- FY’2020 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements (CMS-1714-P)—Received at OMB 3/4/2019, pending review
- FY’2020 Inpatient Psychiatric Facilities Prospective Payment System Rate and Quality Reporting Updates (CMS-1712-P)—Received at OMB 3/6/2019, pending review
- Nondiscrimination in Health Programs and Activities (RIN 0945-AA11)—Received at OMB 4/13/2018, pending review
- CY’ 2020 Home Health Prospective Payment System Rate Update and Quality Reporting Requirements (CMS-1711-P), Received at OMB 3/27/2019, pending review.
- CY’ 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1715-P)—Received at OMB 3/26/2019, pending review.
- CY’ 2020 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-1713-P)—Received at OMB 3/26/2019, pending review
- Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses (CMS-4180-F)—Received at OMB 4/3/2019
- CY’ 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1717-P)—Received at OMB 4/4/2019

- Medicaid Provider Payment Reassignment (CMS-2413-F)—Received at OMB 3/15/2019, pending review
- Regulation to Require Drug Pricing Transparency (CMS-4187-F), Received at OMB 3/18/2019, pending review
- Final Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part C Payment Policies and 2020 Final Call Letter (RIN 0938-ZB52)—Received at OMB 3/20/2019, pending review
- Topical Antimicrobial Drug Products for Over-the-Counter Human Use: Final Monograph for Consumer Antiseptic Rub Products (RIN 0910-AH97)—Received at OMB 2/4/2019
- Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (RIN 0945-AA10)—Received at OMB 1/17/2019, pending review
- Substance Abuse and Mental Health Services Administration Mandatory Guidelines for Federal Workplace Drug Testing Programs (RIN 0930-AA24)—Received at OMB 8/6/2018, pending review
- Confidential Communications (RIN 0930-AA30)—Received at OMB 2/8/2019, pending review
- Revision of Requirements for Long-Term Care Facilities: Arbitration Agreements (CMS-3342-F)—Received at OMB 1/20/2019, pending review
- Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2020 (CMS-4185-F)—Received at OMB 2/28/2019, pending review
- Programs of All-Inclusive Care for the Elderly (PACE) Update (CMS-4168-F)—Received at OMB 3/5/2019, pending review
- Medicaid Provider Payment Reassignment (CMS-2413-F)—Received at OMB 3/15/2019, pending review
- Program Integrity Enhancements to the Provider Enrollment Process (CMS-6058-F)—Received at OMB 12/3/2018, pending review
- Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (RIN 0910-AA10)—Received at OMB 1/17/2019, pending review
- Final Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Final Call Letter (RIN 0938-ZB52)—Received at OMB 3/20/2019, pending review
- Veterans Care Agreements (RIN 2900-AQ45)—Received at OMB 3/12/2019, pending review
- Veterans Community Care Program (RIN 2900-AQ46)—Received at OMB 3/1/2019, pending review

#### **IV. Recent final rules issued-**

- Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) – Effective 10/1/2018 (Ref#15)
- Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNF) Final Rule for FY 2019, SNF Value-Based Purchasing Program, and SNF Quality Reporting Program; Correction— Effective 10/1/2018
- Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims; Correction—Effective 10/1/2018 (Ref#16)
- Annual Civil Monetary Penalties Inflation Adjustment—Effective 10/11/2018
- Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies; Extension of Timeline for Publication of Final Rule—Effective 11/2/2018
- Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organization—Effective 1/1/2019
- Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee

- Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS—Effective 1/1/2019
- Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act—Effective 1/14/2019
  - Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicaid Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act—Effective 1/1/2019
  - 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation—Effective 1/1/2019 (Ref. #12)
  - Patient Protection and Affordable Care Act; Elimination of Internal Agency Process for Implementation of the Federally-Facilitated User Fee Adjustment—Effective 1/3/2019
  - Patient Protection and Affordable Care Act; Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year Final Rule—Effective 2/8/2019
  - Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations-Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017—Effective 2/14/2019
  - Compliance With Statutory Program Integrity Requirements—Effective 5/3/2019
  - Patient Protection and Affordable Care Act; Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year Final Rule

Ref. #	Short Title/Current Status of Regulation/Agency/File Code	Dates (Issued, Due, Action)	Brief Summary of Proposed Agency Action	Summary of NIH and/or TTAG Recommendations	NIHB Analysis
1.	<p>Office of the National Coordinator (ONC) for Health IT Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs</p> <p>ACTION: Public comment AGENCY: ONC FILE CODE: N/A</p>	<p>Published: 11/28/2018</p> <p>Due Date: 1/28/2019</p>	<p>In the <a href="#">21st Century Cures Act</a>, Congress identified the importance of easing regulatory and administrative burdens associated with the use of electronic health records (EHRs) and health information technology. Specifically, Congress directed the Department of Health and Human Services (HHS) to establish a goal, develop a strategy, and provide recommendations to reduce EHR-related burdens that affect care delivery.</p> <p>This draft <i>Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs</i> reflects input HHS has received through several wide-reaching listening sessions, written input, and stakeholder outreach.</p> <p>Based on this input, the draft strategy outlines three overarching goals designed to reduce clinician burden:</p> <ol style="list-style-type: none"> <li>1. Reduce the effort and time required to record health information in EHRs for clinicians;</li> <li>2. Reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and healthcare organizations; and</li> <li>3. Improve the functionality and intuitiveness (ease of use) of EHRs.</li> </ol>	<p><b>NIHB submitted comments on the ONC Draft Strategy on January 28, 2019.</b></p> <p>-NIHB kindly reminded ONC of the challenges that many I/T/U facilities face in relation to RPMS and the inability to keep pace with Commercial-Off-The-Shelf (COTS) EHRs. In parallel, the VA is in the midst of transition to a COTS system, which RPMS receives updates and changes through.</p> <p>NIHB had the following recommendations to the strategies in the Draft Strategy:</p> <p><b>Clinical Documentation:</b></p> <p>-NIHB alluded to the struggles with meeting burdensome requirements imposed by Federal health Care IT systems such as Meaningful Use of CEHRT due to underfunding and lack of adequate infrastructure and policies that do not meet the unique needs of Indian Country.</p> <p>-Reference to E.O. 13175 to facilitate Tribal Consultation and honor the trust responsibility was highlighted.</p> <p><b>Health IT Usability and the User Experience</b></p> <p>-NIHB recommended the ONC Draft Strategy must in its final analysis of clinician burden and clinical workflow include, at minimum, a reference to challenges unique to the I/T/U health care systems when it formulates procedures to implement cross-agency interoperability.</p>	<p>ONC has reviewed and analyzed all submitted comments. The final version of the strategy will be published on <a href="http://www.HealthIT.gov">www.HealthIT.gov</a> in late 2019.</p> <p>After ONC publishes, the final version of the strategy, NIHB will conduct analysis to see if Tribal concerns and recommendations were incorporated into the final product.</p> <p>In this final version, NIHB suggests that the ONC Draft Strategy, in its final version, designate a section to recommend that Federal agencies commit significant resources toward I/T/U HIT requirements, to allow IHS to either update the current EHR or to initiate a process similar to that of the VA. Additionally, it is important that the final strategy recognize that RPMS is dependent on an increasingly antiquated broadband infrastructure that is in dire need of upgrade and expansion.</p>

				<p>-Further, NIHB recommended that ONC include in its final strategy make room for improvement of the health information data entry and maintenance systems, and the data submission process, as required by the Indian health care systems – <b>to maintain its accountability to the Federal government.</b></p> <p><b><i>EHR Reporting</i></b>  -NIHB advocates for, per the draft strategy, that Health IT system revisions must design quality measures that are applicable to individual clinical workflows and to patient care, and at the same time not burden clinicians.</p> <p>Additionally, NIHB made mention of the Quality Payment Programs (QPP) established under MACRA, such as MIPS and APMs. NIHB addressed the compliance costs and how the under-resourced I/T/U system is unable to reach these benchmarks for that reasons along with limited funding. With the move to value-based payment models, NIHB recommends a “collect once, share many” approach when reporting measures across Federal agencies and reiterated that providers have flexibility in terms of what Clinical Quality Measures are reported on for MU.</p> <p>The fiscal aspects on the I/T/U system and the resource gaps in terms of not only clinicians but also IT staff is also addressed.</p> <p><b><i>Public Health Reporting</i></b>  -NIHB recommends that systematic improvements are also needed in Public Health reporting to improve interoperability and health data access between I/T/U and non-I/T/U EHR systems, and</p>	
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				<p>ensure that Public Health surveillance systems and disease registries are matching their records with IHS registries.</p> <p>-NIHB recommends that input from IHS, Tribes and Tribal Epidemiology Centers (TECs) is included.</p>	
2.	<p>21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program ACTION: Proposed Rule AGENCY: ONC FILE CODE: RIN 0955-AA01</p>	<p>Published: 3/4/2019 Due Date: 5/3/2019</p>	<ul style="list-style-type: none"> <li>• ONC is responsible for the implementation of key provisions in Title IV of the 21st Century Cures Act (Cures Act) that are designed to advance interoperability; support the access, exchange, and use of electronic health information; and address occurrences of information blocking.</li> <li>• This proposed rule would implement certain provisions of the Cures Act, including Conditions and Maintenance of Certification requirements for health information technology (health IT) developers, the voluntary certification of health IT for use by pediatric health providers, and reasonable and necessary activities that do not constitute information blocking. In addition, the proposed rule would implement parts of section 4006(a) of the Cures Act to support patient access to their electronic health information (EHI), such as making a patient's EHI more electronically accessible through the adoption of standards and certification criteria and the implementation of information blocking policies that support patient electronic access to their health information at no cost.</li> <li>• Additionally, the proposed rule would modify the 2015 Edition health IT certification criteria and ONC Health IT Certification Program (Program) in other ways to advance interoperability, enhance health IT certification, and reduce burden and costs.</li> </ul>	<p><b>-Recommendations are currently being sought in conjunction with CMS-9115-P.</b></p> <p>-NIHB recommends input from Tribal stakeholders in the I/T/U system and those heavily involved in the development, use of and updating of Health Information Technology.</p>	
3.	<p>Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers ACTION: Proposed Rule AGENCY: CMS FILE CODE: CMS-9115-P</p>	<p>Published: 3/4/2019 Due Date: 5/3/2019</p>	<p>-This proposed rule is the first phase of proposed policies centrally focused on advancing interoperability and patient access to health information using the authority available to the Centers for Medicare &amp; Medicaid Services (CMS).</p> <p>-CMS states this is an important step in advancing interoperability, putting patients at the center of their health care and ensuring they have access to their health information.</p> <p>-CMS states they are committed to solving the issue of interoperability and achieving complete access to health information for patients in the United States (U.S.) health care system, and are taking an active approach to move participants in the</p>	<p><b>-Recommendations are currently being sought in conjunction with RIN 0955-AA01.</b></p> <p>NIHB recommends input from Tribal stakeholders in the I/T/U system and those heavily involved in the development, use of and updating of Health Information Technology.</p>	

			health care market toward interoperability and the secure and timely exchange of health information by proposing and adopting policies for the Medicare and Medicaid programs, the Children's Health Insurance Program (CHIP), and issuers of qualified health plans (QHPs).		
4.	<p>Request for Information: Patient Protection and Affordable Care Act; Increasing Consumer Choice through the Sale of Individual Health Insurance Across State Lines Through Health Care Choice Compacts</p> <p>ACTION: RFI AGENCY: CMS FILE CODE: CMS-9921-NC</p>	<p>Published: 3/11/2019</p> <p>Due Date: 5/6/2019</p>	<p>•CMS is interested in feedback on how states can take advantage of Section 1333 of the Affordable Care Act, which provides for the establishment of a regulatory framework that allows two or more states to enter into a Health Care Choice Compact to facilitate the sale of health insurance coverage across state lines.</p> <p>•Section 1333 allows health insurance issuers to engage in multi-state compacts and sell individual qualified health plan (QHP) products in any state included in the agreement. However, the ACA makes no mention of selling group health insurance plans in the same manner, and no state has specifically passed laws allowing insurers to do so.</p> <p>•CMS is primarily looking for input on how the agency can expand access to health insurance coverage across state lines, effectively operationalize the sale of health insurance coverage across state lines, and understand the financial impacts of selling health insurance coverage across state lines.</p>	<p><b>Recommendations are currently being sought.</b></p> <p>NIHB recommends input from Tribal stakeholder in CMS regions where the health systems is operationalized in more than one state.</p> <p>Located under Section II—Solicitation of Public Comments—B. Operationalizing the Sale of Health Insurance Coverage Across State Lines</p> <p>5. To what extent, if any, would the sale of individual health insurance coverage across state lines pursuant to a Health Care Choice Compact positively or negatively impact the following populations: Persons with pre-existing conditions; persons with disabilities; persons with chronic physical health conditions; expectant mothers; newborns; <b>American Indians and Alaska Natives and tribal entities</b>; veterans; and persons with behavioral health conditions, including both mental health and substance use disorder conditions?</p>	



<p><b>5.</b></p>	<p>Basic Health Program; Federal Funding Methodology for Program Years 2019 and 2020</p> <p>ACTION: Proposed Methodology AGENCY: CMS FILE CODE: CMS-2407-PN</p>	<p>Published: 4/2/2019</p> <p>Due Date: 5/2/2019</p>	<p>Section 1331 of the Affordable Care Act (codified at 42 U.S.C. 18051) requires the Secretary to establish a BHP, and section (d)(1) specifically provides that if the Secretary finds that a state meets the requirements of the program established under section (a) of section 1331 of the Affordable Care Act, the Secretary shall transfer to the State federal BHP payments described in section (d)(3). This proposed methodology provides for the funding methodology to determine the federal BHP payment amounts required to implement these provisions in program years 2019 and 2020.</p>	<p><b>MN and NY</b> are the two states that have implemented Basic Health Programs and in each state, Tribal Consultation had occurred as required by BHP Blueprint in order for a state to make an official request for certification of a BHP. In both instances, Tribes did not provide comments.</p> <p>NIHB staff reached out to a former representative from the state of Minnesota's health insurance Marketplace, known as MNSure. According to this representative, Tribes that subsidize premiums would save money because more people would be insured under BHPs. Additionally, more people insured means Tribes can recover more for the costs of care if patients enroll in plans. In regards to the rate formulas presented in the document, Tribal implications may not be profound.</p>	
<p><b>6.</b></p>	<p>Medicaid Program; Covered Outpatient Drug Line; Line Extension Definition; and Change to the Rebate Calculation for Line Extension Drugs</p> <p>ACTION: Interim Final Rule with comment period AGENCY: CMS FILE CODE: CMS 2345-F2 &amp; 2345-IFC2</p>	<p>Published: 4/1/2019</p> <p>Due Date: 5/31/2019</p> <p>Effective (Interim): 4/1/2019</p>	<p>In this publication to the Federal Register, CMS has issued both a final rule and interim final rule with comment period, which is in response to a final rule released on February 1, 2016. The 2016 final rule did not finalize a regulatory definition of "Line extension" but instead opened a comment period.</p> <p>CMS initially proposed to define "line extension" based on chemical types, per FDA approval records instead of defining it by where a manufacturer received a patient extension. Since then CMS has released Medicaid Drug Rebate Notices when the Comprehensive Addiction and Recovery Act of 2016 (CARA) and the Bipartisan Budget Act (BBA) of 2018 included statutory changes related to line extensions. CARA included a provision to exclude abuse-deterrent formulations from the definition of line extension while the BBA of 2018 updated the rebate amount calculation.</p> <p>Still, there is no concrete definition of "line extension". CMS is instead deferring to the statutory definition.</p>		

			<p>In the Interim final rule with comment period, CMS is updating regulations to reflect current statutory language that was passed in the BBA of 2018.</p> <p>As required by the BBA, rebate periods beginning on or after October 1, 2018 will use the greater of the following to determine the unit rebate amount calculation (URA) for a line extension drug:</p> <ul style="list-style-type: none"> <li>• Standard URA: the basic rebate plus the additional rebate for the line extension drug</li> <li>• Alternative URA: the basic rebate plus the product of the quarterly AMP of the line extension drug and the highest additional rebate for any strength of the original single source drug or innovator multiple source drug</li> </ul>		
7.	<p>Fraud and Abuse: Removal of Safe-Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Managers Service Fees</p> <p>ACTION: Proposed Rule AGENCY: HHS FILE CODE: RIN 0936-AA08</p>	<p>Published: 2/6/2019</p> <p>Due Date: 4/8/2019</p>	<p>In this proposed rule, HHS proposes to amend the safe harbor regulation concerning discounts, which are defined as certain conduct that is protected from liability under the Federal anti-kickback statute, section 1128B(b) of the Social Security Act. The amendment would revise the discount safe harbor to explicitly exclude from the definition of a discount eligible for safe harbor protection certain reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to plan sponsors under Medicare Part D, Medicaid managed care organizations as defined under section 1903(m) of the Act (Medicaid MCOs), or pharmacy benefit managers (PBMs) under contract with them. In addition, the Department is proposing two new safe harbors. The first would protect certain point-of-sale reductions in price on prescription pharmaceutical products, and the second would protect certain PBM service fees.</p>	<p><b>COMMENTS NOT RECOMMENDED</b></p> <p>NIHB reached out to the Pequot Tribe of Connecticut who operate an expansive pharmaceutical network and alluded to the fact that the two primary mechanisms in which Tribes and Tribal organizations receive discounted prescription drugs at a discount are through the 340B and the VA Prime Vendor Program, and inquired as to what the potential ramifications are to these two programs in relation to the proposed rule.</p> <p>According to the Pequot Tribe, Tribes would not be directly affected by the proposed rule because the PBM receives the rebate on the “back end” after the rebate is processed. One of the foreseeable impacts would be if Tribes have employees that are non-Tribal.</p>	
8.	<p>Supplemental Nutrition Assistance Program: Requirements for Able-Bodied Adults Without Dependents</p> <p>ACTION: Proposed Rule AGENCY: USDA FILE CODE: RIN 0584-AE57</p>	<p>Publication Date: 2/1/2019</p> <p>Due Date: 4/2/2019</p>	<ul style="list-style-type: none"> <li>• The focus is on updating the U.S. Department of Agriculture’s (USDA or the agency) standards for approving state waivers to extend SNAP benefits to ABAWDs. ABAWD’s may currently receive benefits for three months in a 36-month period, unless the individual meets certain work requirements. Current regulations</li> </ul>	<p><b>NIHB submitted comments on April 2, 2019.</b></p> <p><b>RECOMMENDATIONS:</b></p> <p>1. Due to lack of adequate tribal consultation in the</p>	

			<p>at 7 CFR 273.24(f) set standards and requirements for the data and evidence that states must provide to FNS to support an ABAWD waiver request. States enjoy considerable flexibility to make these waiver requests under current regulations. According to USDA, this flexibility has resulted in the widespread use of waivers during a given period of low unemployment, which reduces the application of the work requirement.</p>	<p>ANPRM pursuant to EO 13175, Tribes recommend the Agency consult with Tribes before the proposed rule is finalized and before its implementation.</p> <ol style="list-style-type: none"> <li>2. Tribes should be granted flexibility to report unemployment data in a manner that is best suitable for each reservation area.</li> <li>3. Tribes should be exempt from work requirements.</li> <li>4. Tribes support an unemployment floor of 6 percent.</li> <li>5. Tribes oppose the proposed rule's language that the state governor must endorse the state's application for a waiver</li> </ol>	
9.	<p>NIHB and NCAI Joint Comments on HHS Tribal Consultation Policy  ACTION: DTLL Request for Input  AGENCY: HHS  FILE CODE: N/A</p>	<p>Published: 10/22/2018  Due Date: 3/15/2019</p>	<p>Directed to Tribal Leaders on behalf of HHS to ensure that the HHS Consultation policy is meeting the needs of Tribes. HHS is committed to evaluating the policy periodically.</p> <p>Specifically, HHS seeks to gain input on:</p> <ul style="list-style-type: none"> <li>• Review and evaluation the current TCP to provide your feedback on the consultation mechanisms that work and those that do not.</li> <li>• What HHS can do to improve their activities to ensure an effective and meaningful Tribal Consultation Policy?</li> </ul>	<p>A comparative analysis of the HHS TCP and the CMS TCPs had been sent to the MMPC Regulations Workgroups in February 2019.</p> <p>NIHB recommended the formation of a TCP Workgroup to devise comments for the HHS TCP update. As a result, <b>NIHB and NCAI submitted joint comments on March 15, 2019</b>, with the following recommendations:</p> <ul style="list-style-type: none"> <li>-Recommend that STAC form a subcommittee to create procedures for incorporating Tribal feedback into the Tribal Consultation Policy.</li> <li>-Recommend that HHS renumber sections of the TCP so that it is easier to reference.</li> <li>-Recommend that HHS improve Section 8(A)(4), "Receipt of Tribal Comments," by providing that all Tribal comments submitted will be posted on an HHS webpage unless the commenter expressly requests otherwise.</li> </ul>	<p>NIHB has heard that the agency will begin review of Tribal feedback sometime in the fall. NIHB will continue to monitor.</p>

				<p>Specifically recommend adding at the end of Section 8(A)(4): “All comments submitted in writing in response to a request for consultation or a Dear Tribal Leader Letter (“DTLL”) by HHS or any of its Divisions or programs will be posted on an HHS webpage with the expressed consent of the sender. If no expressed consent is given, comments submitted will be included in a final summary of comments received and shared without direct attribution to a specific entity. This summary will be posted on the HHS webpage with the associated request or DTLL.”</p> <p>-Recommend that HHS be specific about the response to the comments received and the timelines for accomplishing tasks or achieving objectives that are identified through Tribal consultations.</p> <p>Recommendations for Definitions and Use of Terms:</p> <p>-Federally Recognized Tribal governments be replaced with “Indian Tribes”.</p> <p>-“Indian”; recommend that the reference be to the definition of Indian in the Indian Self-Determination and Education Assistance Act at 25 U.S.C. § 5304(e) and to other conditions under which individuals are considered by HHS to be Indian.</p> <p>-Indian organizations be replaced with “Tribal organizations”.</p> <p>-Definition of “Indian Tribe” be consistent with ISDEAA.</p> <p>-Tribal government be replaced throughout TCP with “Indian Tribe”.</p> <p>-“Tribal organization” be used in lieu of “Tribal Officials”.</p> <p>-Standard for Action - Recommend that HHS adopt a standard that it</p>	
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				<p>will take various actions addressed by the TCP unless it is prohibited by law from doing so.</p> <p>-Section 10, "Joint Tribal/Federal Workgroups and/or Task Forces." We recommend that HHS clarify that the joint workgroups or task forces formed under the consultation policy are not subject to (or in the alternative are formed to be exempt from) Federal Advisory Committee Act ("FACA") requirements.</p> <p>Substantive Changes:          -Recommend that HHS Tribal Consultation Policy emphasize the Federal trust responsibility to American Indians and Alaska Natives ("AI/ANs"). NIHB, NCAI, and Tribes request that the HHS TCP provide a preamble statement or Introduction that details the Federal trust responsibility to provide health to American Indians and Alaska Natives and the Department's commitment to Tribal consultation in carrying out that responsibility.</p> <p>-Recommend that HHS refer to STAC throughout the policy as having a role that is supportive of HHS, and also include STAC in the Definitions and Acronyms sections.</p> <p>-Recommend that HHS revise the policy to include evaluation and accountability measures in the position description for the agency contact person who will liaison with Tribes.</p> <p>-Recommend enhancing the role of the Office of Intergovernmental Affairs at Section 4(A) under "Policy".</p> <p>-Recommend that the HHS policy emphasize regional</p>	
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				<p>Tribal consultation responsibilities.</p> <p>-Recommend that HHS strengthen agency evaluation, reporting, and accountability procedures by reporting Tribal interactions in a more public forum. Going forward, the annual consultation reports should be published by HHS in a more visible, public, or user-friendly manner.</p> <p>-Recommend that HHS improve Section 8(A), "Communication Methods."</p> <p>-Recommend that HHS not consolidate the regional consultations due to the uniqueness of each area and the significance of dialogue engagement.</p>	
10.	<p>HHS, Office of HIV/AIDS and Infectious Disease Policy Request for Information (RFI): Improving Efficiency, Effectiveness, Coordination, and Accountability of HIV and Viral Hepatitis Prevention, Care, and Treatment Programs  ACTION: Public comment  AGENCY: HHS  FILE CODE: 2019-01695</p>	<p>Published: 2/8/2019  Due Date: 3/11/2019</p>	<p>The U.S. Department of Health and Human Services Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) is offering multiple ways for the public to take an active role in helping to develop the next iterations of the National HIV/AIDS Strategy (NHAS) and the National Viral Hepatitis Action Plan (NVHAP). Both national strategies currently expire in 2020. OHAIDP is combining the commenting process for both the NHAS and the NVHAP, but they will remain separate strategies</p>	<p><b>NIHB submitted comments on March 11, 2019.</b></p> <p>-NIHB expressed on behalf of Tribes, the importance of direct funding to Tribes. Additionally, NIHB stated that it is a more efficient model of resource delivery, it honors the trust responsibility of the federal government, and it empowers Tribal communities to develop and own their prevention, care and treatment programs. It is vital that the plans being developed discuss fair and equitable resource allocation, including direct provision of funding to Tribes.</p> <p>-NIHB strongly recommends that HHS consider developing separate and distinct objectives that apply specifically to AI/AN communities.</p> <p>-Pursuant to EO 13175, the need for Tribal Consultation during Development of HIV and Viral Hepatitis Funding Streams and Initiatives.</p>	

				<p>-NIHB recommends addressing the Cross Cutting Elements of the HIV, Viral Hepatitis and the Opioid Epidemics and promoting collaboration at the Tribal and local levels.</p> <p>-NIHB also stressed the need for Tribally Inclusive Evaluation and Surveillance Systems and that both the NHAS and NVHAP should address the need to evaluate program implementation in a culturally respectful and inclusive manner and alleviate the bureaucratic barriers the TECs experience.</p> <p>-NIHB also stressed the importance of primary prevention, the bolstering of HIV and Viral Hepatitis Testing Efforts, addressing the rural epidemic of which many Tribal communities are located on, mitigating stigma as key driver of epidemics, expanding the support for and use of harm reduction strategies and syringe service programs.</p> <p>-NIHB also stated the importance of the social determinants of health in Indian Country and that the HIV/AIDS strategy and the Viral Hep-C Action Plan create strategies that highlight these concerns within underserved AI/AN communities.</p> <p>-Access to Quality of Care and addressing not only clinical competency but also cultural competency is vital to improving care in AI/AN communities.</p> <p>-NIHB and Tribes also express support for the inclusion of Pharmacists as key clinicians due to their relevance in terms of guidance and support in I/T/U facilities</p> <p>-NIHB advocated for HHS provide adequate funding</p>	
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				for the I/T/U system to treat all patients with chronic HCV, thus reducing the viral load in the community, reducing the burden on the healthcare system, eliminating the costs of longer term treatment, and prolong the life of members of the community.	
11.	Request for Information on Modifying HIPAA Rules To Improve Coordinated Care ACTION: Request for Information AGENCY: OCR FILE CODE: Docket No.: HHS-OCR-0945-AA00 RIN 0945-AA00	Published: 12/14/2018  Due Date: 2/12/2019	<p>Through this RFI, the Office for Civil Rights (OCR) sought public input on ways to modify the HIPAA Rules to remove regulatory obstacles and decrease regulatory burdens in order to facilitate efficient care coordination and/or case management and to promote the transformation to value-based health care, while preserving the privacy and security of protected health information (PHI).</p> <p>Specifically, OCR sought information on the provisions of the HIPAA Rules that may present obstacles to, or place unnecessary burdens on, the ability of covered entities and business associates to conduct care coordination and/or case management, or that may inhibit the transformation of the health care system to a value-based health care system.</p> <p>Correspondingly, OCR sought comment on modifications to the HIPAA Rules that would facilitate efficient care coordination and/or case management, and/or promote the transformation to value-based health care. OCR also broadly requested information and perspectives from regulated entities and the public about covered entities' and business associates' technical capabilities, individuals' interests, and ways to achieve these goals.</p> <p>-Additionally, OCR also sought input on Implementing the HITECH Act requirement to include, in an <b>accounting of disclosures, disclosures for treatment, payment, and health care operations (TPO) from an electronic health record (EHR)</b> in a manner that provides helpful information to individuals, while minimizing regulatory burdens and disincentives to the adoption and use of <b>interoperable EHRs</b>.</p> <p>-Encouraging covered entities, particularly providers, to share treatment information with parents, loved ones, and caregivers of adults facing health emergencies, with a particular focus on the <b>opioid crisis</b>.</p>	<p><b>NIHB submitted comments on February 12, 2019.</b></p> <p>-NIHB recommended for Tribal health systems be permitted disclosure between covered entities for treatment purposes would enhance critical and timely care for some of the most vulnerable populations served (e.g. those with chronic diseases and serious mental illness) who all too often need care from multiple entities.</p> <p>-NIHB expressed on behalf of Tribes the acknowledgement that requests for treatment records would apply for treatment purposes only and not for payment or health care operations, in order to maximize the individual patient's privacy while simultaneously coordinating his or her care in a timely and efficient manner.</p> <p>-NIHB on behalf of Tribes stated that certain PHI should be limited within a designated record set. Sensitive PHI should be excluded from disclosure requirements for covered entities unless the individual or legal representative consent to including these records.</p> <p>-It was also recommended that EHR related PHI requests to the provider be provided within 1-2 business days rather than the current 30-day period.</p> <p>-Verbal consent for the release of PHI from the</p>	



				<p>patient to a covered health care provider.</p> <p>- Aligning HIPAA with 42 CFR Part 2 would allow Information regarding treatment services for co-occurring issues and would simplify mechanisms for providing integrated services internally and externally. It would enable providers to identify areas of need and treatment if they were able to share information seamlessly through EHR with Primary Care Providers (PCP) and other service providers.</p>	
12.	<p>340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation</p> <p>ACTION: Final Rule AGENCY: HRSA FILE CODE: RIN 0906-AB18</p>	<p>Published: 5/7/2018</p> <p>Effective: 1/1/2019</p>	<p>HHS published a notice of proposed rulemaking (NPRM) on June 17, 2015, to implement civil monetary penalties (CMPs) for manufacturers that knowingly and intentionally charge a covered entity more than the ceiling price for a covered outpatient drug; to provide clarity regarding the requirement that manufacturers calculate the 340B ceiling price on a quarterly basis; and to establish the requirement that a manufacturer charge \$.01 (penny pricing) for each unit of a drug when the ceiling price calculation equals zero (<a href="#">80 FR 34583</a>, June 17, 2015).</p> <p>The effective date of the final rule published in the Federal Register on January 5, 2017, at 82 FR 1210, and delayed March 6, 2017 at 82 FR 12508, March 20, 2017 at 82 FR 14332, May 19, 2017 at 82 FR 22893, September 29, 2017 at 82 FR 45511, and June 5, 2018 at 83 FR 25944, is changed to <b>January 1, 2019</b>.</p>	<p><b>NIHB submitted comments on May 22, 2018.</b></p> <p>NIHB reminded HRSA for the purposes of the 340B program, an FQHC defined as including "an outpatient health program or facility operated by a Tribe or Tribal organization under the Indian Self-Determination and Education Assistance Act ... or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act ... for the provision of primary health services." 42 U.S.C. § 1396d(l)(2)(B)(iv). Also, the Tribal health program can register as the "covered entity".</p> <p>NIHB stressed the importance of the 340B program to the I/T/U system, which is already severely underfunded. The primary ways in which Tribes receive prescription pharmaceuticals is through the 340B and the VA Pharmaceutical Prime Vendor Program (PPV), which NIHB also reiterated.</p> <p>NIHB asserted that AI/ANs are one of the most vulnerable populations and at 80 Fed Reg. at 52300 which states the</p>	<p>NIHB requested Tribal Consultation per EO 13175 before any final rule is implemented.</p> <p>HHS implemented the final rule, effective January 1, 2019. No Tribal Consultation occurred.</p>

				<p>intent of the 340B program is to “ to permit covered entities 'to stretch Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'” This reinforces the importance of the 340B program and if there are instances where manufactures are shorting Tribal health programs, then CMPs must be in place to ensure monetary funds are paid to I/T/U facilities.</p>	
13.	<p>Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020</p> <p>ACTION: Proposed Rule AGENCY: CMS FILE CODE: CMS-9926-P RIN 0938-AT37</p>	<p>Published: 1/24/2019</p> <p>Due Date: 2/19/2019</p> <p>Received at OMB: 3/22/2019, pending review</p>	<p>This proposed rule sets forth payment parameters and provisions related to the risk adjustment and risk adjustment data validation programs; cost-sharing parameters; and user fees for Federally-facilitated Exchanges (FfEs) and State-based Exchanges on the Federal Platform (SBE-FPs). It proposes changes that would allow greater flexibility related to the duties and training requirements for the Navigator program and proposes changes that would provide greater flexibility for direct enrollment entities, while strengthening program integrity oversight over those entities. It proposes policies that are intended to reduce the costs of prescription drugs. It includes proposed changes to Exchange standards related to eligibility and enrollment; exemptions.</p> <ul style="list-style-type: none"> <li>•CMS seeks comments on whether there are any existing regulatory barriers that stand in the way of privately led efforts at pricing transparency, and ways that we can facilitate or support increased private innovation in pricing transparency.</li> <li>•As part of CMS’s efforts to empower consumers in their health care decisions, CMS seeks comment on how the agency can promote transparency for consumers and value- based insurance design.</li> <li>•CMS seeks comment on ways that we can promote the offering and take-up of High Deductible Health Plans (HDHPs) that can be paired with Health Savings Accounts (HSAs), which can serve as an effective and tax-advantageous method for certain consumers to manage their health care expenditures.</li> </ul> <p>-CMS is particularly interested in comments that address ways to increase the visibility of HSA-eligible HDHPs on HealthCare.gov.</p>	<p><b>TTAG submitted comments on February 19, 2019.</b></p> <p>-The TTAG supports keeping the Marketplace stable so that health coverage is affordable for AI/ANs, and thus encourages CMS to continue to mitigate instability in the Marketplace. The TTAG recommends that CMS continue to allow issuers to silver load until a legislative solution is achieved by Congress. In addition, the TTAG recommends that silver loading remain an option to improve affordability and attract issuers and enrollees to the Marketplace.</p> <p>-The TTAG expressed concerns that if the proposed rule is implemented, Marketplace plans will be in favor of lowering the user fee and switching pharmacy benefits mid-year. Moreover, the proposed rule’s changes come at the expense of the beneficiary and is not be in the best interest of the consumers.</p> <p>The prospect of formulary changes is a consumer protection issue, since insurers’ ability to switch plans and prescription drugs without adequate notice to the beneficiary is</p>	<p>The proposed Rule was received at OMB on March 22, 2019 and currently pending review. Once final rule is implemented, regulatory analysis will be conducted to assess whether Tribal concerns were addressed in the preamble of the final rule from TTAG’s comments.</p>

				to the detriment of the consumer. The Administration has asked whether advanced notice should number 120 days.  The TTAG agrees that notice should be provided with a minimum of 120 days, but advocates that mid-formulary changes be prohibited by this rule.	
14.	<p>Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNF) Final Rule for FY 2019, SNF Value-Based Purchasing Program, and SNF Quality Reporting Program; Correction</p> <p>ACTION: Final Rule, Correction AGENCY: CMS FILE CODE: CMS-1696-CN RIN 0938-AT24</p>	<p>Published: 10/3/2018</p> <p>Effective: 10/1/2018</p>	<p>Errors in Preamble:</p> <ul style="list-style-type: none"> <li>• There were a number of technical errors that were identified and corrected. The provisions in this correcting document are effective October 1, 2018.</li> <li>• In the FY 2019 SNF PPS final rule, errors were made in copying values into the “total rate” column of the tables used in the final rule preamble, so the numbers in this column did not accurately reflect the total case-mix adjusted federal per diem rates. A typographical error in Table 27 in the MDS item number reference (column 2) associated with one of the conditions and extensive services used for NTA classification. Additionally, in Table 45 on page 39285 of the FY 2019 SNF PPS final rule, there was a mistake in the ordering of the ownership labels in the table as “Government, Profit, Non-Profit”, instead of “Profit, Non-Profit, Government.” Lastly, an error in an inadvertent typo was made in relation to “urban rural West South Central region,” when it was intended to state “rural West South Central region.”</li> </ul> <p>Errors in Tables posted to CMS website:</p> <ul style="list-style-type: none"> <li>• CMS corrected the wage indexes in Tables A and B setting forth the wage indexes for urban areas based on CBSA labor market areas (Table A) and the wage indexes for rural areas based on CBSA labor market areas (Table B), which are available exclusively on the CMS website at <a href="http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html">http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html</a>.</li> </ul>	No recommendations for this correction.	CMS states that correcting the document does not constitute a rule that would be subject to the notice and comment or delayed effective date requirements. This document corrects technical errors in the FY 2019 SNF PPS final rule and in the tables referenced in the final rule, but does not make substantive changes to the policies or payment methodologies that were adopted in the final rule. As a result, this correction notice is intended to ensure that the information in the FY 2019 SNF PPS final rule accurately reflects the policies adopted in that final rule.
15.	<p>Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs)</p>	<p>Published: 8/17/2018</p> <p>Effective 10/1/2018</p>	<ul style="list-style-type: none"> <li>• The final rule is effective October 1, 2018 and revises the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from continuing experiences with these systems for FY 2019.</li> <li>• These revisions also reflect changes to Medicare graduate medical education (GME)</li> </ul>	<p><b>NIHB submitted comments on June 25, 2018.</b></p> <p>NIHB submitted recommendations regarding:</p> <p><b>-Hospital Acquired Conditions Measures:</b></p> <p>NIHB expressed concerns over the potential impact</p>	<ul style="list-style-type: none"> <li>• Upon review and subsequent analyses of CMS 1694-F (effective 10/1/18); in relation to the HAC measures, CMS is not finalizing their proposals to remove any of the six patient safety measures, with PSI-90 being one of those measures.</li> </ul>

	<p>ACTION: Final Rule          AGENCY: CMS          FILE CODE: CMS-1694-F</p>		<p>affiliation agreements for new urban teaching hospitals.</p> <ul style="list-style-type: none"> <li>• Effective January 1, 2019, CMS will update its guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or more often as appropriate.</li> <li>• Additionally, CMS is updating policies for the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.</li> </ul>	<p>of proposed alternative scoring methodologies for calculating total Hospital Acquired Conditions scores. Small rural, hospitals have scores that are low because they had less than 1.0 predicted infections for all other measures which resulted in 85% of their HAC score and a two year penalty. In the rule, CMS proposes to either, remove the domains and weight all measures equally, or to limit the maximum Domain 2 weight from 85% to 60% when only one Domain 2 measure is scored. However, rural hospitals will still be penalized. Therefore, NIHB recommends the review of the PSI-90 measure as a whole and its presence in any kind of payment reform.</p> <p>-In light of this, NIHB recommend that CMS establish an exclusion for low volume hospitals, or further refine the methodology to achieve the desired result and accurately depict performance of rural hospitals.</p> <p><b>-Graduate Medical Education:</b></p> <p>-NIHB recommends that Medicare funding be eligible for IHS and Tribal hospitals so there is a funding stream for residency programs and could boast to be a more powerful recruitment and retention tool which is needed in Indian Country.</p> <p><b>-Requirements for Hospitals to Make Public List of Standard Charges:</b></p> <p>-Effective January 1, 2019, CMS will update its guidelines to require hospitals to make available</p>	<p>CMS further stated they are not finalizing their proposal to remove the Safety domain from the Hospital Value-Based Purchasing (VBP) Program, as they are not finalizing their proposals to remove all of the measures in that domain, therefore CMS is not finalizing changes to the domain weighting.</p> <ul style="list-style-type: none"> <li>•CMS agreed that small sample sizes may have negative implications for hospital quality measures (e.g. HACs) due to limited sample sizes and ultimately limit the statistical reliability of reporting by race or other sociodemographic measures and that they are not consistently captured in claims. Therefore, CMS will continue to examine how best to improve the collection of such data.</li> <li>•In regards to GME, this item was addressed in the final rules' Out of Scope Public Comments section: "Indian Health Service and Tribal Hospitals be made eligible to receive Medicare funding for residency training programs; CMS felt comments related to the aforementioned item were out of scope for the proposal included in the FY'19 IPPS/LTCH PPS proposed rule."</li> </ul>
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				<p>a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or more often as appropriate. To address this, CMS is considering ways to improve the accessibility and usability of the charge information that hospitals are required to disclose under section 2718(e) of the Public Health Service Act.</p> <p>-NIHB feels it is critically important to note that beneficiaries of the Indian health system do not have to pay for care that they receive from IHS, Tribal, and urban Indian health programs. Since IHS and Tribal hospitals do not charge its patients for services it would be extremely difficult for Indian health providers to develop fee for service schedules that private hospitals maintain in the course of their day to day operations.</p>	<p>•According to CMS, the prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. As stated within CMS 1694-F, “There were 29 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals.”</p>
16.	<p>Medicare Program; Hospital Prospective Payment System for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Records (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals; Critical Access Hospitals and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims; Correction  ACTION: Final Rule, Correction  AGENCY: CMS  FILE CODE: CMS-1694-CN2  RIN 0938-AT27</p>	<p>Published: 10/3/2018   Effective: 10/1/2018</p>	<p>In FR Doc. <a href="#">2018-16766</a> of August 17, 2018 (<a href="#">83 FR 41144</a>) there were a number of technical and typographical errors that are identified and corrected by the Correction of Errors section of this correcting document. The provisions in this correcting document are effective as if they had been included in the document that appeared in the August 17, 2018 <b>Federal Register</b>. Accordingly, the corrections are effective October 1, 2018.</p>	<p>No recommendations for this correction.</p>	<p>Please see analysis in previous reference to this final rule.</p>

<p><b>17.</b></p>	<p>Health and Human Services (HHS): Healthy People 2030</p> <p>ACTION: Public Comment AGENCY: HHS FILE CODE: N/A</p>	<p>Published: 12/3/2018</p> <p>Due Date: 1/17/19</p>	<ul style="list-style-type: none"> <li>• Every decade, the Healthy People initiative develops a new set of science-based, 10-year national objectives with the goal of improving the health of all Americans. The development of Healthy People 2030 includes establishing a framework for the initiative—the vision, mission, foundational principles, plan of action, and overarching goals—and identifying new objectives.</li> </ul>	<p><b>NIHB Submitted comments on January 17, 2019.</b></p> <p>The HP2030 framework identified 41 health topic areas that span a wide spectrum of health priorities. Each of the topic areas certainly impact Tribal health, there are cross-cutting considerations that transcend any one particular area. Tribes and NIHB believe these considerations are critical for HHS and federal agencies to consider as they formulate strategies for implementing the HP2030 objectives. These cross-cutting considerations represent some of the systemic challenges that limit the ability of Tribes to improve health outcomes across multiple health conditions.</p> <p>The following recommendations and/or concerns were addressed by NIHB:</p> <ul style="list-style-type: none"> <li>-Lack of IHS and Tribal Representation on the Secretary’s Advisory Committee</li> <li>-Need for Indian Country Specific Topics and Objectives under the Healthy People Framework</li> <li>-Need for Tribal Consultation During Development of Healthy People Framework and Objectives</li> <li>-Additionally, there were “Access to Services” concerns NIHB commented in relation to increasing number of AI/ANs on medical insurance, alleviating the number of AI/ANs with delays in care, decreasing ED visits.</li> <li>-Chronic diseases that afflict AI/ANs such as: Cancer, Chronic Kidney</li> </ul>	<p>The Secretary’s Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 will carefully review all the comments and proposed objectives received. These public comments will help inform the final Healthy People 2030 objectives. NIHB will perform subsequent analysis when the new iteration of Healthy People 2030 is released.</p>
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				<p>Disease, Diabetes along with SDPI implications.</p> <p>Other areas that NIHB highlighted include:  Environmental Health, Education and Community Based Programs, Health Information Technology, Heart Disease and Stroke, HIV, LGBT Health, Mental Health, Maternal and Child Health, Nutrition, Opioids, Oral Health, Preparedness, Public Health Infrastructure, Sexually Transmitted Infections (STIs), Social Determinants of Health, Substance and Tobacco Use.</p>	
18.	<p>State of Oklahoma request to amend the State’s Section 1115(a) “SoonerCare” Choice Program</p> <p>NOTICE: Federal comment period  AGENCY: CMS  FILE CODE: N/A</p>	<p>Published: 12/20/2018</p> <p>Due Date: 1/18/2019</p>	<ul style="list-style-type: none"> <li>Oklahoma proposes to amend its demonstration to add community engagement requirements as a condition of eligibility for certain individuals age 19 through 50</li> </ul>	<p>NIHB submitted comments on January 18, 2019.</p> <p>NIHB noted to strong presence of Tribes in Oklahoma and the trust responsibility afforded to Tribes in the provision of health services.</p> <p>NIHB also supplemented the commentary with letters from the Choctaw and Chickasaw Nations.</p> <p>Collectively, Tribes support the amendments proposition of exempting AI/ANs under Section 6 of the application.</p>	<p>Oklahoma’s waiver application is currently pending. NIHB will continue to monitor the status of this application.</p>
19.	<p>Medicaid Program; Medicaid and Children’s Health Insurance Plan (CHIP) Managed Care</p> <p>NOTICE: Proposed Rule  AGENCY: CMS  FILE CODE: CMS-2408-P</p>	<p>Published: 11/14/2018</p> <p>Due Date: 1/14/2019</p>	<ul style="list-style-type: none"> <li>This proposed rule advances CMS’ efforts to streamline the Medicaid and Children’s Health Insurance Plan (CHIP) managed care regulatory framework and reflects a broader strategy to relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care. These proposed revisions of the Medicaid and CHIP managed care regulations are intended to ensure that the regulatory framework is efficient and feasible for states to implement in a cost-effective manner and ensure that states can implement and operate Medicaid and CHIP managed care programs without undue administrative burdens.</li> </ul>	<p>TTAG submitted comments on January 14, 2019.</p> <p>NIHB and Tribes asserted that Managed Care Organizations (MCOs) often have little to no familiarity with the Indian health system and routinely disregard the rights of AI/ANs and Indian health providers under the Medicaid statute, the Indian Health Care Improvement Act, and other federal laws. AI/ANs continue to find it difficult to access Indian health care providers (IHCPs) in managed care settings, and IHCPs continue to have difficulties being reimbursed by the Medicaid program from MCOs.</p>	

				<p>Other recommendations:</p> <p>-CMS must ensure that the AI/AN protections from mandatory managed care in Section 1932(a)(2)(C) of the Social Security Act apply across the board, including through Section 1115 Demonstration Waivers.</p> <p>-CMS must ensure that the Section 5006 of the American Recovery and Reinvestment Act of 2009 (ARRA) Medicaid managed care protections are meaningfully implemented in the managed care regulations pertaining to AI/ANs and Indian health providers who voluntarily elect to enroll in managed care.</p> <p>-CMS must ensure that other provisions of the rule account for the unique status and needs of the Indian health system.</p> <p>-NIHB and Tribes also reiterated previous concerns relating to the lack of parity between MCOs and ICHPs in regard to contractual and reimbursement issues.</p> <p>-Further, it is recommended that existing standards that were adopted from the 2016 Managed Care regulations be maintained.</p> <p>-Another notable concern were the Quality Rating System (QRS) and the proposal to omit CMS prior approval for QRS measures. Tribes voiced concerns that these measures would be left at the discretion of the state which could negatively impact Tribes within MCO based systems.</p>	
20.	Substance Abuse and Mental Health Services Administration (SAMHSA): State Opioid Response (SOR) and Tribal Opioid Response (TOR) Program	Published: 12/10/2018  Due Date: 1/9/2019	<ul style="list-style-type: none"> <li>The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) is requesting approval from the Office of Management and Budget (OMB) for data collection</li> </ul>	<p><b>NIHB submitted comments on January 9, 2019.</b></p> <p>-NIHB reminded SAMHSA that Tribes submit client-</p>	



	<p>Data Collection and Performance Measurement</p> <p>ACTION: Notice with Request for Comment  AGENCY: SAMHSA  FILE CODE: 2018-26659</p>		<p>activities associated with the State Opioid Response (SOR) and Tribal Opioid Response (TOR) discretionary grant programs. Approval of this information collection will allow SAMHSA to continue to meet the Government Performance and Results Modernization Act of 2010 (GPRMA) reporting requirements that quantify the effects and accomplishments of its discretionary grant programs which are consistent with OMB guidance. Information collected through this request will be used to monitor performance throughout the grant period.</p>	<p>level data through GPRA and stated that SOR/TOR grantees may have difficulty in locating the reference tools when reporting through GPRA. Tribes also stated the NOFO did not provide clear direction in terms of measures and where in the application reporting requirements are listed.</p> <p>-In addition, the invasiveness of the questions posed presented issues and Tribes expressed greater autonomy not just for the clients but for the purposes of the SOR/TOR project to collect meaningful data. Time required for data collection should also be more realistic for providers in Indian Country who may lack the FTE and/or the resources necessary.</p>	
<p>21.</p>	<p>State of Virginia’s Medicaid Section 1115 Demonstration Application  Virginia GAP and ARTS Delivery System Transformation – Extension Request</p> <p>ACTION: Request for Public Comment  AGENCY: CMS  FILE CODE: N/A</p>	<p>Published: 12/7/2018  Due Date: 1/6/2019</p>	<p>-As a condition of Medicaid coverage under Virginia COMPASS, adults ages 19 to 64 with incomes up to 138 percent of the FPL, who do not otherwise qualify for an exemption, must engage in qualifying work or community engagement activities. These include employment, self-employment, job training or job search activities, participation in a state workforce program, education and vocational training, and community service.</p> <p>-The hour requirement will gradually increase over time. It begins at 20 hours per month for the first three months and increases to 40 hours per month six months after enrollment, 60 hours per month nine months after enrollment, and 80 hours per month 12 months after enrollment.</p> <p>-Non-exempt enrollees who fail to comply with their work requirements for three consecutive or non-consecutive months within a 12-month period will have their coverage suspended. Enrollees whose coverage is suspended as a result of non-compliance may have their coverage reinstated upon the end of the 12-month period of an enrollee’s coverage year, demonstrating compliance with the requirements for one month, qualifying for another Medicaid eligibility category not subject to work requirements,</p>	<p><b>NIHB supported the comments made on behalf of the United South and Eastern Tribes Sovereignty Protection Fund (USET SPF) opposing Virginia’s Section 1115 Waiver application proposing work requirements, with their letter supplementing NIHBs comments as an attachment.</b></p> <p>NIHB also included as a supplement, NIHB Resolution 18-19, Support for Exempting IHS Eligible Beneficiaries from Medicaid Work and Community Engagement Requirements</p>	<p>NIHB will be monitoring subsequent action from both CMS and the state of Virginia regarding the outcome of this waiver application.</p>

			<p>qualifying for a standard or hardship/good cause exemption, or turning age 65. The Commonwealth estimates 120,000 individuals will be subject to the work requirement.</p> <p>-The waiver will build on Virginia’s existing workforce programs, including the Virginia Workforce Centers and the VEC, to extend available employment supports services to participants. Employment supports will include education supports, pre-vocational supports, and individual and small group supports.</p>		
22.	<p>Comments to CDC: Formative and Summative Evaluation of the National Diabetes Prevention Program in Underserved Areas</p> <p>ACTION: Notice with Comment Period  AGENCY: CDC  FILE CODE: Docket No. CDC-2018-0089</p>	<p>Published: 10/4/2018</p> <p>Due Date: 12/3/2018</p>	<ul style="list-style-type: none"> <li>This notice is in relation to the proposed project from the National Center for Chronic Disease and Prevention and Health Promotion (NCCDPHP) within CDC entitled: Formative and Summative Evaluation of Scaling the National Diabetes Prevention Program in Underserved Areas (OMB No. 0920-1090, exp. 12/31/2018).</li> <li>OMB expressed particular interest in comments that would help: <ul style="list-style-type: none"> <li>Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;</li> <li>Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;</li> <li>Enhance the quality, utility, and clarity of the information to be collected; and</li> <li>Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.</li> <li>Assess information collection costs.</li> </ul> </li> </ul>	<p><b>NIHB submitted comments on December 3, 2018.</b></p> <p>-NIHB requested that CDC take into consideration the <b>lack</b> of availability of internet access and barriers for rural Tribal health care organizations to obtain a vast up-to-date IT infrastructure and make efforts to accommodate non-electronic reporting submission.</p> <p>-NIHB recommended that CDC take into account the unique nature of the I/T/U system in relation program reporting and lack of FTE to fulfill reporting requirements. NIHB recommended that reporting requirements also be streamlined in concert with another Diabetes program known as SDPI administered by IHS and HHS.</p> <p>-NIHB reiterated Tribal Consultation pursuant to EO 13175.</p>	
23.	<p>Comments to CDC: Surgeon Generals Call To Action: “Community Health And Prosperity”; Establishment of a Public Docket</p> <p>ACTION: Notice with comment period  AGENCY: CDC  FILE CODE: Docket No. CDC-2018-0082</p>	<p>Published: 9/6/2018</p> <p>Due Date: 11/5/2018</p>	<p>CDC is the lead agency to support the Office of the Surgeon General to publish a Call to Action that will be science-informed and actionable, outlining a conceptual framework with case examples and available evidence on the business case for investing in community health.</p> <p>The goal of the Call to Action is to:</p>	<p><b>NIHB submitted comments on November 5, 2018.</b></p> <p>-NIHB provided statistics relating to the current public health status in Indian Country and the fact that AI/ANs</p>	

			<p><b>Clearly demonstrate that investments in community health have the potential to improve the health and prosperity of communities and issue a call to action to the private sector and local policy makers for investment in communities, unilaterally or as part of multi-sector or other consortium, to improve community health.</b></p>	<p>experience some of the worst health outcomes.</p> <p>-The concept of community health and the accompanying social determinants are concepts already embedded within Tribal Nations in the form of traditional teaching and cultural values. That being said, NIHB asserted that Tribal public health programs be developed by and for Tribes and this has been exemplified in many diverse tribal communities in addressing health priorities.</p> <p>-NIHB requested Tribal Consultation pursuant to EO 13175.</p>	
24.	<p>State of Alabama Medicaid Workforce Initiative Section 1115 Demonstration Application</p> <p>ACTION: Request for public comment AGENCY: CMS FILE CODE: N/A</p>	<p>Published: 9/21/2018</p> <p>Due Date: 10/21/2018</p>	<p>Through this waiver application, Alabama requests a new 5-year section 1115 demonstration which seeks to require community engagement as a condition of continued Medicaid eligibility for able-bodied parent or caretaker relative beneficiaries to improve beneficiary health outcomes and economic stability. Beneficiaries will be required to participate in 35 hours a week of community engagement activities unless the beneficiary is a parent or caretaker relative with a child under 6 years of age, lowering the requirement to 20 hours per week. Failure to comply with the requirements will result in termination of Medicaid benefits</p>	<p><b>NIHB submitted comments on October 21, 2018.</b></p> <p>-NIHB emphasized the trust responsibility afforded to Tribes as well as it being highlighted in HHS' Strategic Plan.</p> <p>-NIHB acknowledged the presence of the Poarch Band of Creek Indians who are the only federally recognized Tribe in the state of Alabama and that advancements of Medicaid's objectives apply to all Tribes.</p>	<p>This waiver application is currently pending.</p>
25.	<p>Healthy Michigan Plan Section 1115 Demonstration Waiver Joint Comments with National Council of Urban Indians (NCUIH)</p> <p>ACTION: Amendment request with public comment period AGENCY: CMS FILE CODE: N/A</p>	<p>Published: 9/26/2018</p> <p>Due Date: 10/26/2018</p>	<ul style="list-style-type: none"> <li>Michigan proposed to amend its demonstration, "Healthy Michigan Plan." The state is requested that in order for beneficiaries with income between 100 percent and 133 percent of the federal poverty level (FPL) to maintain eligibility after 48 months of cumulative enrollment, they must engage in annual healthy behaviors and non-exempt beneficiaries must pay a monthly 5 percent of income premium as a condition of continued Medicaid eligibility.</li> <li><b>The state is also requested the authority to require beneficiaries to participate in community engagement requirements as a condition of continued Medicaid eligibility.</b></li> </ul>	<p>NIHB, NCUIH and TSGAC submitted joint comments on October 26, 2018.</p> <p>The "national organizations" express caution in merely including Tribal employment programs in the list of qualifying activities offers no protection nor does it uphold the Federal trust responsibility.</p> <p>The national organizations also mention the implications this demonstration could have on a woefully underfunded I/T/U system.</p>	<p>CMS approved Michigan's waiver application on December 21, 2018.</p> <p>In CMS' letter to the state of Michigan, CMS acknowledged commenters concerns the demonstration would exacerbate racial health disparities, with particular emphasis on Native American communities.</p> <p><b>There are no exemptions for AI/ANs but CMS state however, that</b></p>

					<p><b><i>Tribal employment training programs are in the list of qualifying activities.</i></b></p> <p>On February 8, 2019, Michigan's new governor, Gretchen Whitmer submitted a letter to CMS accepting the Special Terms and Conditions (STCs) for its work requirements waiver but also mentions the Michigan Department of Health and Human Services would be submitting its requested technical corrections in a subsequent letter.</p>
26.	<p>Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP</p> <p>ACTION: Request for Information (RFI) AGENCY: CMS FILE CODE: OIG-0803-N</p>	<p>Published: 8/27/2018</p> <p>Due Date: 10/26/2018</p>	<ul style="list-style-type: none"> <li>• This request for information (RFI) seeks input from the public on how to address any regulatory provisions that may act as barriers to coordinated care or value-based care.</li> <li>• The RFI harkens back to HHS' "Regulatory Sprint" which is focused on identifying regulatory provisions that may act as barriers to coordinated care, assessing whether those regulatory provisions are unnecessary obstacles to coordinated care, and issuing guidance or revising regulations to address such obstacles and, as appropriate, to encourage and incentivize coordinated care while protecting against harms caused by fraud and abuse.</li> <li>• The Office of Inspector General (OIG) seeks to identify ways in which it might modify or add new safe harbors to the anti-kickback statute and exceptions to the beneficiary inducements civil monetary penalty (CMP) definition of "remuneration" in order to foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse.</li> </ul>	<p><b>TTAG submitted comments on October 26, 2018.</b></p> <p>-TTAG referenced previous letters and consultations the group had made in the past with OIG in relation to proposed safe harbors for Indian Health Care Providers (IHCPs).</p> <p>-TTAG recommended that Indian health programs have parity with FQHCs under the anti-kickback statute and other federal health care fraud and abuse laws. Attached to the letter is TTAG's proposed American Indian and Alaska Native and Indian Health Care Provider Safe Harbors. Specifically, to amend 42 C.F.R. § 1001.952.</p> <p>-TTAG and Tribes state that AKS and CMP are substantial impediments to care coordination and innovation as it might be enforced in the Indian health system, particularly through Purchased/Referred Care (PRC) and care coordination agreements with non-Tribal providers,</p>	

				which are needed to overcome barriers to care coordination and sharing of resources between the I/T/U system and other providers.	
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