available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH''. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mrs. Traci Whitfield, Bridge Administration Branch Fifth District, Coast Guard, telephone (757) 398–6629, email *Traci.G.Whitfield@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Event Director for the New Bern Mumfest, with approval from the North Carolina Department of Transportation, owner of the drawbridge, has requested a temporary deviation from the current operating regulations set out in 33 CFR 117.843(a) to accommodate safe passage for pedestrians and vehicles during Mumfest.

The US 70 (Alfred C. Cunningham) Bridge is a double bascule lift bridge and has a vertical clearance in the closed position of 14 feet above mean high water. Under this temporary deviation, the drawbridge will open every two hours, on the hour, from 9 a.m. through 8 p.m. on Saturday, October 8, 2016 and from 9 a.m. through 7 p.m. on Sunday, October 9, 2016. From 8 p.m. on Saturday, October 8, 2016 through 9 a.m. on Sunday, October 9, 2016, the drawbridge will open on signal.

Vessels able to pass under the bridge in the closed position may do so at anytime. Mariners are advised to proceed with caution. The bridge will be able to open for emergencies and there is no alternate route for vessels unable to pass through the bridge in the closed position. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 16, 2016.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2016–06266 Filed 3–18–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

42 CFR Part 136

RIN 0917–AA12

Payment for Physician and Other Health Care Professional Services Purchased by Indian Health Programs and Medical Charges Associated With Non-Hospital-Based Care

AGENCY: Indian Health Service, HHS.

ACTION: Final rule with comment period.

SUMMARY: The Secretary of the Department of Health and Human Services (HHS) hereby issues this final rule with comment period to implement a methodology and payment rates for the Indian Health Service (IHS) Purchased/Referred Care (PRC), formerly known as the Contract Health Services (CHS), to apply Medicare payment methodologies to all physician and other health care professional services and non-hospital-based services. Specifically, it will allow the health programs operated by IHS, Tribes, Tribal organizations, and urban Indian organizations (collectively, I/T/U programs) to negotiate or pay non-I/T/U providers based on the applicable Medicare fee schedule, prospective payment system, Medicare Rate, or in the event of a Medicare waiver, the payment amount will be calculated in accordance with such waiver; the amount negotiated by a repricing agent, if applicable; or the provider or supplier's most favored customer (MFC) rate. This final rule will establish payment rates that are consistent across Federal health care programs, align payment with inpatient services, and enable the I/T/U to expand beneficiary access to medical care. A comment period is included, in part, to address Tribal stakeholder concerns about the opportunity for meaningful consultation on the rule's impact on Tribal health programs.

DATES: *Effective date:* These final regulations are effective May 20, 2016.

Comment date: IHS will consider comments on this final rule with comment period received at one of the addresses provided below, no later than May 20, 2016.

Compliance and applicability dates: A health program operated by the IHS or by an urban Indian organization through a contract or grant under Title V of the Indian Health Care Improvement Act (IHCIA), Public Law 97–437 must implement the rates specified herein no later than March 21, 2017. The rule will apply to outpatient services provided after May 20, 2016. The rule will apply to inpatient services with an admission that falls on or after the effective date of the rule.

ADDRESSES: You may submit comments in one of four ways (please choose only one of the ways listed):

- *Electronically.* You may submit electronic comments on this regulation to *http://regulations.gov.* Follow the ''Submit a Comment'' instructions.
- *By regular mail.* You may mail written comments to the following address ONLY: Betty Gould, Regulations Officer, Indian Health Service, Office of Management Services, 5600 Fishers Lane, Mailstop 09E70, Rockville, Maryland 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.
- *By express or overnight mail.* You may send written comments to the above address.
- *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to the address above.

If you intend to deliver your comments to the Rockville address, please call telephone number (301) 443–1116 in advance to schedule your arrival with a staff member. Comments will be made available for public inspection at the Rockville address from 8:30 a.m. to 5 p.m., Monday–Friday, no later than three weeks after publication of this notice.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

FOR FURTHER INFORMATION CONTACT: Ms. Terri Schmidt, Acting Director, Indian Health Service, Office of Resource Access and Partnerships, 5600 Fishers Lane, Mailstop 10E85–C, Rockville, Maryland 20857, telephone (301) 443–2694. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: The Consolidated Appropriation Act of 2014 signed by President Obama in January 2014, adopted a new name, Purchased/Referred Care (PRC), for the CHS program. The name change was official with passage of the Fiscal Year (FY) 2014 appropriation. The new name better describes the purpose of the program funding, which is for both purchased care and referred care outside of IHS. The name change does not change the program, and all current policies and practices will continue and is not intended to have any effect on the laws that govern or apply to CHS. IHS will administer PRC in accordance with

all laws applicable to CHS. This final rule will use the term PRC.

I. Background

On December 5, 2014, the Department published proposed regulations in a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (79 FR 72160) to amend the IHS medical regulations at 42 CFR part 136 by adding a new subpart I to apply Medicare payment methodologies to all physician and other health professional services and non-hospital-based services provided through CHS, now PRC, or purchased by urban Indian organizations. In the NPRM, the Department invited the public to comment on the proposed provisions; subsequently, in a **Federal Register** document published on January 14, 2015 (80 FR 1880), the 45-day comment period was extended to February 4, 2015. Under 42 CFR 136.23, when necessary services are not reasonably accessible or available to IHS beneficiaries, the IHS and Tribes are authorized to pay for medical care provided to IHS beneficiaries by non-IHS or Tribal, public or private health care providers, depending on the availability of funds. Similarly, under section 503 of the IHCIA, 25 U.S.C. 1653, urban Indian organizations may refer eligible urban Indians, as defined under section 4 of the IHCIA, to non-I/T/U public and private health care providers and, depending on the availability of funds, may also cover the cost of care. The PRC Program is authorized to pay for medical care provided to IHS beneficiaries by non-IHS or Tribal, public or private health care providers, depending on the availability of funds. I/T/Us reimburse for authorized services at the rates provided by contracts negotiated at the local level with individual providers or according to a provider's billed charges. Given the small market share of individual I/T/U programs, I/T/Us historically have paid rates in substantial excess of Medicare's allowable rates or rates paid by private insurers for the same services. Despite establishing medical priorities to cover the most necessary care, IHS is still unable to provide care to all of its beneficiaries. The demand for PRC care consistently exceeds available funding. IHS recently reported to Congress that IHS and tribal PRC programs denied an estimated $760,855,000 for an estimated 146,928 contract care services needed by eligible beneficiaries in FY 2013. This rule finalizes the Medicare-like rates NPRM and ensures PRC programs reimburse non-hospital services, including physician services, at rates comparable to other federal programs; the savings realized by adopting and implementing this rule will increase patient access to care.

II. Provisions of the Proposed Regulations

a. The Proposed Rule

HHS proposed to amend the regulations at 42 CFR part 136 by adding a new Subpart I to describe the payment methodologies to all physician and health care professional services and all non-hospital-based services that are not covered currently under 42 CFR part 136 subpart D. The final rule would amend the regulation at 42 CFR part 136, by adding a new Subpart I to apply the Medicare payment methodologies to all physician and other health professional services and non-hospital-based services purchased by an IHS or Tribal PRC program, or urban Indian organizations.

b. Summary of Changes in the Final Rule

IHS has added an applicability provision in § 136.201. This provision specifies that the rule applies to IHS-operated PRC programs, urban Indian health programs, and Tribally-operated programs, but only to the extent the Tribally-operated programs opt-in to the requirements of the rule. IHS has added a definition section to the rule at § 136.202. In that section, important terms used in the rule are defined, including Notification of a Claim, Provider, Supplier, Referral and Repricing Agent. In § 136.203 (§ 136.201 of the NPRM), flexibility to allow PRC programs to negotiate rates that are higher than Medicare rates is added. With a narrow exception, the discretion to negotiate rates equal to or less than rates accepted by the provider or supplier's MFC is limited. In the absence of a negotiated amount, the amount the provider or supplier bills the general public is eliminated from the methodology and replaced with the amount the provider or supplier accepts from its MFC.

III. Analysis of and Responses to Public Comments

The Agency received 57 comments from Tribes, Tribal organizations, medical associations, and individuals. The Agency carefully reviewed the submissions by individuals, groups, Indian and non-Indian organizations. IHS did not consider three of these comments, because they were received after the closing date. Of the 54 timely comments, nine commenters supported the proposed regulation; thirty-eight commenters support the proposed regulation with changes; three commenters did not support the proposed regulation; and four commenters provided general comments.

Comment: The majority of commenters support the rule as a positive step toward achieving the goal of expanding PRC rates to non-hospital-based providers and suppliers. Many commenters stated the rule's potential impact on individual providers would be diffuse and de minimus and that the proposed rule would provide an enormous benefit to the IHS and Tribal health care programs. Commenters noted that IHS and Tribal health programs often pay higher payment rates than private health insurers and other Federal programs, such as Medicare and the Veterans Health Administration. In addition, many commenters suggested that implementing rates for non-hospital-based providers will increase the volume of services being sought which will result in providers achieving more volume to offset the decrease in rates.

Response: IHS agrees with the commenters that this rule is necessary and important towards achieving payment parity with other Federal health care programs.

Comment: There were a number of commenters that support the proposed rule, but with changes. Several commenters expressed the view, that as drafted, the proposed rule does not provide enough flexibility to ensure continued access to care through the PRC program. Specifically, many commenters felt that a rigid take-it-or-leave-it rate structure would result in many health care providers refusing to do business with I/T/Us. Many Tribal stakeholders recommended providing Tribal and urban Indian health programs with the option to negotiate higher rates, but to limit maximum rates to what the provider or supplier would accept from non-governmental payers, including insurers, for the same service. Advocates for non-IHS and Tribal providers also recommended incorporating flexibility to negotiate rates.

Response: IHS highlighted concerns about the impact the rule could have on access to care in the preamble to the NPRM and was pleased with the thoughtful responses received. IHS agrees with commenters that more flexibility must be built into the rule. IHS also agrees with Tribal stakeholders that Tribes should be provided more flexibility to negotiate rates that exceed Medicare rates and agrees that controls should be put into place to ensure that negotiated rates remain fair and

reasonable. Section 136.203 provides that if a specific amount has been negotiated with a specific provider or supplier or its agent by the I/T/U, the I/T/U will pay that amount, provided such amount is equal to or better than the provider or supplier's MFC rate, as evidenced by commercial price lists or paid invoices and other related pricing and discount data, to ensure the I/T/U is receiving a fair and reasonable pricing arrangement. Further, the MFC rate does not apply if the I/T/U determines the prices offered to the I/T/U are fair and reasonable and the purchase of the service is otherwise in the best interest of the I/T/U. It will be incumbent on the provider of services to provide the necessary documentation to ensure the rates charged are fair and reasonable.

Comment: In addition to the ability to negotiate rates under the rule, several Tribal stakeholders also want an opt-out clause from the proposed rule for Tribal and urban Indian health care programs. The majority of commenters feel Tribal sovereignty and self-determination must also be respected to allow the Tribes the flexibility to negotiate with providers and determine how best to meet the needs of their community when providing health care. They indicated that flexibility is one of the foundational principles underlying the Indian Self-Determination and Education Assistance Act (ISDEAA) and Tribes and Tribal organizations that negotiate agreements under that Act with the IHS should have the right to choose not to apply this new rule.

Response: IHS agrees with Tribal stakeholders that Tribal health programs should have the option to administer PRC programs outside of the rule. Rather than memorialize this option as an opt-out clause, IHS is finalizing the recommendation as an opt-in provision in section 136.201. The opt-in provision is intended to be consistent with 25 U.S.C. 458aaa–16(e), which provides, with certain exceptions, that Tribes are not subject to rules adopted by the IHS unless they are expressly agreed to by the Tribe in their compact, contract or funding agreement with IHS. Although 25 U.S.C. 458aaa–16(e) only expressly applies to Tribes compacted under Title V of the ISDEAA, IHS is extending opt-in flexibility to Tribes contracted under Title I of the ISDEAA too. IHS is not incorporating a comparable provision allowing urban Indian health programs to opt-in or opt-out of the requirements of the rule. Urban Indian health programs are funded through procurement contracts or grants with IHS, not ISDEAA contracts, and the principles underlying self-determination and the opt-in flexibility do not extend to such agreements.

Comment: One commenter believes that reducing physician payments will provide a disincentive to participate in the PRC program and will result in less beneficiary access to care.

Response: IHS acknowledges the implementation of rates could impact access to care, and believe sufficient language has been incorporated to ensure that beneficiary access to care is not compromised.

Comment: One commenter believes the rule would magnify the existing disparity between the average ambulance provider's total costs and their reimbursement.

Response: The implementation of the rule is not intended to require a provider or supplier to incur a financial loss. To the extent the Medicare rate structure results in the provider or supplier incurring a financial loss, the flexibility added to the final rule should permit providers and suppliers to negotiate fair and reasonable rates with I/T/Us.

Comment: The majority of commenters stated that IHS should also engage in provider outreach and monitoring to ensure the rule is effectively implemented. Further, once the final rule is issued, the IHS, in collaboration with Tribes, should develop and issue a ''Dear provider letter'' for all I/T/Us to educate their network of providers regarding this regulation. Commenters believe that education and outreach to providers will be a critical component in successfully implementing the rule.

Response: IHS agrees. IHS took similar steps when it promulgated the hospital-based rate under 42 CFR part 136 subpart D. IHS intends to work with Tribes to educate the providers that participate in IHS and Tribal PRC programs.

Comment: One commenter indicates that some IHS Area Offices utilize case management to better monitor the services that are being purchased through PRC. The commenter proposed that IHS Area Offices have a medical physician on staff for utilization review.

Response: IHS agrees with the commenter but the proposal offered is beyond the scope of this final rule.

Comment: One commenter is concerned that the amount a provider ''bills the general public'' for the same service is too vague. The term ''general public'' is subject to multiple interpretations. The commenter recommended limiting payment to the amount the provider ''accepts as payment for the same service from nongovernmental entities, including insurance providers.''

Response: IHS agrees with the commenter that the proposed language may be open to more than one interpretation. To avoid multiple interpretations and to align this subsection with others changes made to § 136.203, the reference to ''bills the general public'' has been deleted and provisions have been inserted providing for payment not to exceed the provider or supplier's MFC rate, as evidenced by commercial price lists or paid invoices and other related pricing and discount data to ensure that the I/T/U is receiving a fair and reasonable pricing arrangement. Additionally, in the event that a Medicare rate does not exist for an authorized item or service, and no other payment methodology provided by the rule is applicable, IHS has included a provision in 136.203(a)(3) that authorizes payment at 65% of authorized charges.

Comment: The majority of commenters believe the rule should not imply that professional services are never covered by the existing PRC regulations. The current PRC rate regulations apply to ''all Medicare participating hospitals, which are defined for purposes of that subpart to include all departments and provider-based facilities of hospitals.'' The commenters believe this includes physicians and other health care professionals if they are employed directly by the hospital or even ''under arrangements.''

Response: The PRC rate regulations at part 136 subpart D apply to hospitals and critical access hospitals pursuant to section 1866(a)(1)(U) of the Social Security Act which requires providers to agree to provide services under the Contract Health Services, now PRC, program or other programs funded by IHS through the execution of a Medicare participating provider agreement. The agreement executed by hospitals and critical access hospitals under section 1866 does not govern payment for professional services under Medicare, even for services provided by physician employees of a hospital or for ''billing under arrangements,'' and, accordingly, does not generally govern the acceptance of payment for services under Medicare Part B. To eliminate any confusion, the terms Supplier and Provider have been defined in § 136.201 to only include entities that are not subject to Part 136 Subpart D. Supplier means a physician or other practitioner, a facility, or other entity (other than a provider) not already governed by or subject to 42 CFR part 136 subpart D, that furnishes items or services under

this new Subpart. Provider, as used in this subpart only, means a provider of services not governed by or subject to 42 CFR part 136 subpart D, and may include a skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice program.

Comment: The majority of commenters requested training for Tribes. Many commenters suggested IHS develop a training and technical assistance initiative to prepare I/T/U sites to implement the rule. Tribes expressed concern about the lack of training and technical assistance associated with the implementation of the regulation for Payment to Medicare-participating hospitals for authorized CHS (42 CFR 136.30). IHS should work with several software products the I/T/Us can use and commenters recommended that IHS negotiate a volume discount for Tribes to purchase the software.

Response: IHS agrees that training is necessary to ensure that the rule is implemented properly and effectively. Many suggestions for training, however, are beyond the scope of this final rule and will be addressed through subsequent communication with Tribes.

Comment: Commenters indicated that IHS should also develop and implement a process in consultation with Tribes to monitor and report on the success of the rule once it is implemented.

Response: IHS agrees that monitoring the effectiveness of the rule is important. Obtaining data from programs that are implementing the rule is essential to determining its success; however, reporting requirements exceed the scope of this final rule.

Comment: The majority of commenters stated that the proposed rule would have significant Tribal implications and substantial direct effects on one or more Indian Tribes. As a result, pursuant to the HHS Tribal Consultation Policy, Tribal consultation is required. Tribes stated in their comments that they welcomed the opportunity to comment on the proposed rule through the notice and public comment process required by the Administrative Procedure Act, but they stated that the Director of the IHS must also engage in Tribal consultation on the proposed rule before any action is taken to finalize this rule.

Response: IHS consulted with Tribes, during listening sessions and other meetings, on whether Tribes thought IHS should pursue applying PRC rates for non-hospital-based services. It has been noted that while these interactions indicated that regulations may have been a good idea, the level of discussion did not get into the complexities of developing a regulation and how such regulations would impact Tribes given the variation in access to specialty care and the number of hospitals across the Indian health system. IHS recognizes that specific provisions of the rule were not developed in consultation with Tribes. In the development of this final rule, however, IHS has collaborated significantly with the Director's PRC Workgroup. The PRC workgroup is composed of technical experts who have a deep understanding of the complexities of administering PRC programs. The rule has been revised to provide the flexibility many Tribal stakeholders have requested, and as finalized, will not apply to any Tribally-operated PRC program until it elects to opt-in in accordance with § 136.201. IHS recognizes that these steps may not relieve all concerns regarding Tribal consultation. Accordingly, IHS is also publishing this final rule with a comment period in which to receive additional feedback from stakeholders, to determine whether any revisions should be made to the rule.

Comment: One commenter recommended IHS pursue legislation, not a regulation.

Response: Regulations (or rules) implement the public policy of enacted legislation and establish specific requirements. IHS bases its authority on 42 U.S.C. 2003 to establish the methodology and payment rates for the IHS PRC.

Comment: One commenter is concerned that there is nothing explicit in the regulation that prevents the provider from avoiding the Medicare rate by choosing not to submit a claim at all, and seeking redress from the patient directly. Because the Medicare rates may be substantially lower than the provider's billed rate, the providers might avoid a PRC claim entirely and bill the patient for the full amount. The commenter is also concerned that more patients will be taken to collection agencies when they cannot afford to pay when the provider bills the patients directly.

Response: IHS recognizes that the rule does require providers to accept payment from PRC programs and understands that this may on occasion result in patients incurring financial responsibility. IHS beneficiaries already incur financial responsibility for care that IHS cannot cover. In FY 2013, PRC denied an estimated $760,855,000 for an estimated 146,928 services needed by eligible American Indian and Alaska Native individuals. Those numbers only account for IHS administered programs. IHS notes incurring financial responsibility may be avoided by obtaining a PRC authorized referral from IHS prior to treatment. If a referral is issued by IHS, it means that the provider has accepted IHS payment rates, and the patient may not be charged for the service. A definition section was added to the rule at § 136.202 and defined Referral there to clarify for beneficiaries and providers when the requirements for payment acceptance have been triggered. IHS also added a definition for Notification of a Claim, as it too triggers payment acceptance under the rule. Finally, the definition of Repricing Agent was moved to the newly created definition section.

Comment: One commenter stated there needs to be some oversight by either Centers for Medicare & Medicaid Services or other appropriate agencies written into the regulation that includes a way in which all Medicare-participating medical providers have to, by law, accept PRC patients and accept the rates established by 42 CFR part 136 subpart D.

Response: No changes will be made as a result of this comment. IHS is promulgating this rule pursuant to its own rulemaking authority, under which there is no basis for another agency to enforce compliance.

Comment: The majority of commenters state that any changes made, or proposed in the PRC program, must be careful to not adversely impact the effectiveness of the PRC programs. Any change to improve the efficiency or financial operations of the PRC program must be carefully evaluated to ensure that they do not impose additional administrative or financial burdens on the PRC program and the patients they serve. A meaningful and well-intentioned change could actually restrict access and cost the program more resources than it would save.

Response: IHS believes these concerns have been addressed through the flexibilities which have been added to the final rule, the training IHS intends to offer to PRC administrators, and the outreach and education IHS intends to provide to PRC-participating providers and suppliers.

Comment: Some commenters expressed serious concern regarding the long delay between publication of the proposed rule and issuing the final rule on limiting charges for services furnished by Medicare participating inpatient hospitals to individuals eligible for care purchased by Indian health programs, as provided for by Sec. 506 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Once this final rule is adopted,

they stated, it should be implemented in a reasonable but expedient manner.

Response: IHS acknowledges the concern and provides that the rule will be effective 60 days from publication and applicable to services provided after the effective date. The rule will apply to outpatient services provided after the effective date of the rule. The rule will apply to inpatient services with an admission that falls on or after the effective date of the rule. However, IHS also recognizes programs may not be fully equipped to implement the rule when it becomes effective. In accordance with 42 CFR 136.201(c), Tribal health programs may choose to opt-in to the rule immediately, or whenever they are able to fully implement the rule. A health program operated by the IHS or by an urban Indian organization through a contract or grant under Title V of the IHCIA, Public Law 94–437 should implement the rule as soon as possible, but must implement the rates specified herein no later than one year from the date of publication in the **Federal Register**.

IV. Collection of Information Requirements

These regulations do not impose any new information collection requirements. Specifically, federal acquisition regulations already govern the collection of contractor pricing data and agency regulations and procedures already govern the collection of information necessary to process claims. The IHS will use the IHS purchase order form number IHS–843 for collection of information. OMB No. 0917–0002.

V. Regulatory Impact Statement

The IHS has examined the impact of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). An April 2013 study released by the Government Accountability Office (GAO) found that if Federal PRC programs had paid Medicare rates for physicians' services in 2010, they could have realized an estimated $32 million in annual savings to pay for additional services.

The GAO formulated its estimate using actual IHS data, which it obtained from the IHS fiscal intermediary. The GAO narrowed those claims to payments for physician and other nonhospital services. These are the same services at issue in this final rule. Since IHS is the payer of last resort, the GAO excluded services where IHS would not have had primary responsibility, such as services covered by the patient's insurance or another third party payer. The GAO also excluded nonhospital services that were not covered by the Medicare Physician Fee Schedule, as well as anesthesiologists, based upon lack of information to determine comparable Medicare rates.

Once the GAO had isolated the necessary IHS payment data, the GAO compared the IHS payments to the corresponding rate on the 2010 Medicare Physician Fee Schedule. The GAO adjusted the payment rates according to the physician's approximated geographic location and the service setting, based upon Medicare practice. The GAO also compared the IHS payments to those that would have been made by private insurers using a commercial claims and encounters database. The GAO specifically compared payments for services occurring in the same county to account for any variation in payments due to location, by averaging the rate paid by the private insurers for a service in each county and comparing that average rate with IHS payments in the same county.

The GAO evaluated the reliability of the data it had relied upon in its estimates, including the IHS claims data, the Medicare Physician Fee Schedule data, and the private insurance database. The GAO reviewed the documentation and discussed the database with officials it considered knowledgeable in this area. The GAO also performed data reliability checks to test the internal consistency and reliability of the data. The GAO determined that the data was sufficiently reliable for its purposes after taking these steps.

IHS agrees with the methodology utilized by the GAO in its report to select, verify, and compare the necessary elements of the GAO estimate. While the GAO study did not consider the additional flexibility added to this final rule at the request of Tribes or payments made to anesthesiologists, IHS anticipates that most PRC programs and PRC payments under this final rule will closely follow the policy that the GAO considered when developing its study. For this reason, the GAO estimate from the April 2013 study is applicable to the regulatory impact analysis of the final rule.

In 2014, IHS performed an analysis similar to the GAO study with claims data from the IHS fiscal intermediary for fiscal year (FY) 2012. Instead of analyzing the entire IHS system, as GAO had done with data from 2010, IHS focused on the potential impact to IHS PRC programs in the states of North and South Dakota. IHS was able to closely review the specific contracts in place between IHS and physicians in these two states by narrowing the geographic focus of its analysis. IHS found that North Dakota providers who had an agreement in place with IHS during FY 2012 would have received, on average, 31% less if payment rates for professional services and non-hospital-based care had been capped at the Medicare rate, while South Dakota providers would have experienced the opposite and received, on average, 31% more. It is important to note that, of those providing PRC services in FY 2012, only 15–16% had an agreement with IHS in either of these two states. The remaining 84–85% did not have an agreement in place with IHS in FY 2012 and IHS estimates that these providers would have been paid, on average, 35% less in North Dakota and 52% less in South Dakota if the payments had been capped at Medicare rates. While most of the providers without an agreement would have been paid less under this analysis, IHS estimated that 26% in North Dakota and 21% in South Dakota would have received higher payments, because their billed charges were less than the Medicare rates.

Overall, IHS estimated that in FY2012, it could have saved $2,074,638.28 in North Dakota and $5,498,089.09 in South Dakota if PRC payments for professional services and non-hospital-based care had been capped at the Medicare rates. IHS noted that referral numbers and authorizations for payment are dependent on appropriation levels for each year. The estimates provided by the IHS study were based upon the specific factors for FY 2012, including rates and funding levels in place at that point in time. The IHS analysis looked closely at the potential impact on providers in these two states, but it did not perform all of the detailed steps taken by the GAO to determine potential savings. Based upon its limited analysis, though, IHS determined that capping the PRC rates for professional services and non-hospital-based care would likely result in savings for IHS PRC programs.

Both the GAO study and the IHS analysis note the possible consequences of this policy change. The GAO study determined that providers overall would receive less if the payments for professional services and non-hospital-based care are capped at the applicable Medicare rates. The IHS analysis acknowledged that most providers, especially those without a contract with IHS, would receive less under such a policy change, but IHS also found that some providers would receive more per individual claim. During the interview portion of its study, the GAO spoke with a few providers who already had contracts with IHS to be paid at or below Medicare rates. IHS also estimated that adverse impacts on providers could be mitigated by the additional referrals that would result from the PRC savings. In addition to the providers, the GAO study noted possible concerns regarding access to care for patients. The IHS analysis did not delve into this particular issue. However, neither the GAO study nor the IHS analysis anticipated the additional flexibility that would be built into this final rule, as part of the policy change. If IHS finds that providers in particular areas are choosing not to participate based upon the change in policy and the supply of providers in that area is not sufficient to meet demand, thereby impacting patient access to care, IHS has certain flexibility to negotiate higher rates under this final rule to ensure that patients are not negatively impacted. Tribally-operated PRC programs will have the same flexibility, if they choose to opt-in to this final rule. IHS beneficiaries as a whole will be able to benefit from the change in policy, since the savings will allow IHS to provide additional PRC services.

Although the GAO study and the IHS analysis did not include other types of non-hospital services or funding that goes to Tribal PRC programs, particular Tribes and tribal organizations may decide not to opt-in to this final rule. Even if all of the Tribally-operated PRC programs choose to participate, IHS estimates that the increase in purchasing power brought about by this final rule would be unlikely to exceed $100 million annually. Furthermore, if any PRC programs utilize the additional flexibility added to this final rule and choose to negotiate rates above the applicable Medicare rates, the impact would be even less likely to exceed $100 million annually. Office of Management and Budget (OMB) has determined that this is a significant regulatory action under Executive Order 12866.

The Secretary has determined this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the RFA, 5 U.S.C. 601–612. The final rule will not cause significant economic impact on health care providers, suppliers, or entities since only a small portion of the business of such entities concern IHS beneficiaries. The April 2013 study released by the GAO found that of the physicians sampled, the PRC program represented a small portion of their practice and was not a significant source of revenue. Although the sampling of physicians was small, all of the sampled physicians were in the top 25% in terms of volume of paid services covered by PRC. IHS believes the sample to be representative of higher volume practitioners currently providing services paid for by PRC. Accordingly, pursuant to 5 U.S.C. 605(b), the final rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose requirements mandate expenditure in any one year by State, local, or Tribal governments, in the aggregate, or by the private sector, of $141 million. This proposal would not impose substantial Federal mandates on State, local or Tribal governments or private sector.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

List of Subjects in 42 CFR Part 136

American Indian, Alaska Natives, Health, Medicare.

Dated: March 11, 2016.

Mary Smith,

Principal Deputy Director, Indian Health Service.

Dated: March 11, 2016.

Sylvia M. Burwell,

Secretary.

For the reasons set forth in the preamble, the Indian Health Service is amending 42 CFR part 136 as set forth below:

PART 136—INDIAN HEALTH

■ 1. The authority citation for part 136 continues to read as follows:

Authority: 25 U.S.C. 13; sec. 3, 68 Stat. 674 (42 U.S.C., 2001, 2003); Sec. 1, 42 Stat. 208 (25 U.S.C. 13); 42 U.S.C. 2001, unless otherwise noted.

■ 2. Add subpart I, consisting of §§ 136.201 through 136.204, to read as follows:

Subpart I—Limitation on Charges for Health Care Professional Services and Non-Hospital-Based Care

Sec.

Subpart I—Limitation on Charges for Health Care Professional Services and Non-Hospital-Based Care

§ 136.201 Applicability.

The requirements of this Subpart shall apply to:

(a) Health programs operated by the Indian Health Service (IHS).

(b) Health programs operated by an urban Indian organization through a contract or grant under Title V of the Indian Health Care Improvement Act (IHCIA), Public Law 94–437, as amended.

(c) Health programs operated by an Indian Tribe or Tribal organization pursuant to a contract or compact with the IHS under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450 *et seq.*), provided that the Indian Tribe or Tribal organization has agreed in such contract or compact to be bound by this Subpart pursuant to 25 U.S.C. 450l and 458aaa–16(e), as applicable.

§ 136.202 Definitions.

For purposes of this subpart, the following definitions apply.

Notification of a claim means, for the purposes of part 136, and also 25 U.S.C. 1621s and 1646, the submission of a claim that meets the requirements of 42 CFR 136.24.

(1) Such claims must be submitted within the applicable time frame specified by 42 CFR 136.24, or if applicable, 25 U.S.C. 1646, and include information necessary to determine the relative medical need for the services and the individual's eligibility.

(2) The information submitted with the claim must be sufficient to:

(i) Identify the patient as eligible for IHS services (*e.g.*, name, address, home or referring service unit, Tribal affiliation),

(ii) Identify the medical care provided (*e.g.*, the date(s) of service, description of services), and

(iii) Verify prior authorization by the IHS for services provided (*e.g.,* IHS purchase order number or medical referral form) or exemption from prior

authorization (*e.g.,* copies of pertinent clinical information for emergency care that was not prior-authorized).

(3) To be considered sufficient notification of a claim, claims submitted by providers and suppliers for payment must be in a format that complies with the format required for submission of claims under title XVIII of the Social Security Act (42 U.S.C. 1395 *et seq.*) or recognized under section 1175 of such Act (42 U.S.C. 1320d–4).

Provider, as used in this subpart only, means a provider of services not governed by or subject to 42 CFR part 136 subpart D, and may include, but not limited to, a skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice program.

Referral means an authorization for medical care by the appropriate ordering official in accordance with 42 CFR part 136 subpart C.

Repricing agent means an entity that offers an IHS, Tribe or Tribal organization, or urban Indian organization (I/T/U) discounted rates from non-I/T/U public and private providers as a result of existing contracts that the non-I/T/U public or private provider may have within the commercial health care industry.

Supplier, as used in this subpart only, means a physician or other practitioner, a facility, or other entity (other than a provider) not already governed by or subject to 42 CFR part 136 subpart D, that furnishes items or services under this Subpart.

§ 136.203 Payment for provider and supplier services purchased by Indian health programs.

(a) Payment to providers and suppliers not covered by 42 CFR part 136 subpart D, for any level of care authorized under part 136, subpart C by a Purchased/Referred Care (PRC) program of the IHS; or authorized by a Tribe or Tribal organization carrying out a PRC program of the IHS under the Indian Self-Determination and Education Assistance Act, as amended, Public Law 93–638, 25 U.S.C. 450 *et seq.;* or authorized for purchase under § 136.31 by an urban Indian organization (as that term is defined in 25 U.S.C. 1603(h)) (hereafter collectively ''I/T/U''), shall be determined based on the applicable method in this section:

(1) If a specific amount has been negotiated with a specific provider or supplier or its agent by the I/T/U, the I/T/U will pay that amount, provided that such amount is equal to or better than the provider or supplier's Most Favored Customer (MFC) rate, as evidenced by commercial price lists or paid invoices and other related pricing and discount data to ensure that the I/T/U is receiving a fair and reasonable price. The MFC rate limitation shall not apply if:

(i) The prices offered to the I/T/U are fair and reasonable, as determined by the I/T/U, even though comparable discounts were not negotiated; and

(ii) The award is otherwise in the best interest of the I/T/U, as determined by the I/T/U.

(2) If an amount has not been negotiated in accordance with paragraph (a)(1) of this section, the I/T/U will pay the lowest of the following amounts:

(i) The applicable Medicare payment amount, including payment according to a fee schedule, a prospective payment system or based on reasonable cost (''Medicare rate'') for the period in which the service was provided, or in the event of a Medicare waiver, the payment amount will be calculated in accordance with such waiver.

(ii) An amount negotiated by a repricing agent if the provider or supplier is participating within the repricing agent's network and the I/T/U has a pricing arrangement or contract with that repricing agent.

(iii) An amount not to exceed the provider or supplier's MFC rate, as evidenced by commercial price lists or paid invoices and other related pricing and discount data to ensure that the I/T/U is receiving a fair and reasonable price, but only to the extent such evidence is reasonably accessible and available to the I/T/U.

(3) In the event that a Medicare rate does not exist for an authorized item or service, and no other payment methodology provided for in paragraph (a)(1) or (2) of this section are accessible or available, the allowable amount shall be deemed to be 65% of authorized charges.

(b) Coordination of benefits and limitation on recovery: If an I/T/U has authorized payment for items and services provided to an individual who is eligible for benefits under Medicare, Medicaid, or another third party payer—

(1) The I/T/U is the payer of last resort under 25 U.S.C. 1623(b);

(2) If there are any third party payers, the I/T/U will pay the amount for which the patient is being held responsible after the provider or supplier of services has coordinated benefits and all other alternate resources have been considered and paid, including applicable co-payments, deductibles, and coinsurance that are owed by the patient;

(3) The maximum payment by the I/T/U will be only that portion of the payment amount determined under this section not covered by any other payer;

(4) The I/T/U payment will not exceed the rate calculated in accordance with paragraph (a) of this section (plus applicable cost sharing); and

(5) When payment is made by Medicaid it is considered payment in full and there will be no additional payment made by the I/T/U to the amount paid by Medicaid.

(c) Authorized services: Payment shall be made only for those items and services authorized by an I/T/U consistent with this part 136 or section 503(a) of the IHCIA, Public Law 94–437, as amended, 25 U.S.C. 1653(a).

(d) No additional charges:

(1) If an amount has not been negotiated under paragraph (a)(1) of this section, the health care provider or supplier shall be deemed to have accepted the applicable payment amount under paragraph (a)(2) of this section as payment in full if:

(i) The services were provided based on a Referral, as defined in § 136.202; or,

(ii) The health care provider or supplier submits a Notification of a Claim for payment to the I/T/U; or

(iii) The health care provider or supplier accepts payment for the provision of services from the I/T/U.

(2) A payment made and accepted in accordance with this section shall constitute payment in full and the provider or its agent, or supplier or its agent, may not impose any additional charge—

(i) On the individual for I/T/U authorized items and services; or

(ii) For information requested by the I/T/U or its agent or fiscal intermediary for the purposes of payment determinations or quality assurance.

(e) IHS will not adjudicate a notification of a claim that does not contain the information required by § 136.24 with an approval or denial, except that IHS may request further information from the individual, or as applicable, the provider or supplier, necessary to make a decision. A notification of a claim meeting the requirements specified herein does not guarantee payment.

(f) No service shall be authorized and no payment shall be issued in excess of the rate authorized by this section.

§ 136.204 Authorization by an urban Indian organization.

An urban Indian organization may authorize for purchase items and services for an eligible urban Indian as those terms are defined in 25 U.S.C. 1603(f) and (h) according to section 503 of the IHCIA and applicable regulations.

Services and items furnished by physicians and other health care professionals and non-hospital-based entities shall be subject to the payment methodology set forth in § 136.203.

[FR Doc. 2016–06087 Filed 3–18–16; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket Nos. 10–51 and 03–123; FCC 16–25]

Structure and Practices of the Video Relay Service Program; Telecommunications Relay Services and Speech-to-Speech Services for Individuals With Hearing and Speech Disabilities

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission modifies its four-year compensation rate plan for Video Relay Service (VRS), adopted in 2013, by temporarily ''freezing'' the rate of compensation paid from the Interstate Telecommunications Relay Services Fund (TRS Fund) to VRS providers handling 500,000 or fewer monthly minutes and directs the TRS Fund administrator to pay compensation to such providers at a rate of $5.29 per VRS minute for a 16-month period.

DATES: Effective April 20, 2016.

FOR FURTHER INFORMATION CONTACT: Robert Aldrich, Consumer and Governmental Affairs Bureau, at 202–418–0996 or email *Robert.Aldrich@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Structure and Practices of the Video Relay Service Program and Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* Report and Order, document FCC 16–25, adopted on March 1, 2016, and released on March 3, 2016, in CG Docket Nos. 10–51 and 03–123. The full text of document FCC 16–25 will be available for public inspection and copying via ECFS, and during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. Document FCC 16–25 can also be downloaded in Word or Portable Document Format (PDF) at: *https://www.fcc.gov/general/disability-rights-office-headlines.* To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Final Paperwork Reduction Act of 1995 Analysis

Document FCC 16–25 does not contain new or modified information collection requirements subject to the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Congressional Review Act

The Commission will not send a copy of FCC 16–25 pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A), because the Commission adopted no rules therein, as defined in 5 U.S.C. 804(3). Rather, the Commission modified the rates applicable to compensation paid to VRS providers from the TRS Fund.

Synopsis

1. In 2013, the Commission adopted a Report and Order amending its telecommunications relay service (TRS) rules to improve the structure, efficiency, and quality of the VRS program, reduce the risk of waste, fraud, and abuse, and ensure that the program makes full use of advances in commercially-available technology. *Structure and Practices of the Video Relay Services Program, Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CG Docket Nos. 10–51, 03–123, Report and Order and Further Notice of Proposed Rulemaking, published at 78 FR 40407, July 5, 2013 (*VRS Reform Order*), and 78 FR 40582, July 5, 2013 (*VRS Reform FNPRM*), *aff'd in part and vacated in part sub nom. Sorenson Communications, Inc.* v. *FCC,* 765 F.3d 37 (D.C. Cir. 2014) (*Sorenson*). The *VRS Reform Order* established the rates at which VRS providers are compensated from the Interstate Telecommunications Relay Service Fund (TRS Fund) for a four-year period beginning July 1, 2013, and adopted structural reforms designed to establish a more level playing field for all VRS providers.

2. Pursuant to the TRS rules, VRS providers submit the number of minutes of service they provide to the TRS Fund administrator on a monthly basis and are compensated for these minutes based on rates set annually by the Commission. The Commission currently uses a three-tier compensation rate structure that allows smaller providers to receive more compensation per minute, on average, than larger providers. A tiered compensation rate structure allows providers to earn a higher compensation rate on the initial minutes of service provided each month. Pursuant to the three-tiered VRS rate structure as modified in the *VRS Reform Order,* the Tier I rate (the highest rate) applies to a provider's first 500,000 monthly VRS minutes, the Tier II rate applies to a provider's second 500,000 monthly minutes, and the Tier III rate (the lowest rate) applies to monthly minutes in excess of 1,000,000. As a result, smaller providers receive more compensation per minute, on average, than larger providers.

3. In the *VRS Reform Order,* the Commission recognized a need to better align VRS compensation rates with the allowable costs of this service, pending a further determination as to VRS compensation methodology. To that end, and as an alternative to immediately reducing rates to a level based on average costs, the Commission adopted a four-year schedule that gradually adjusts the VRS compensation rates downward every six months, beginning July 1, 2013, and ending June 30, 2017. (In document FCC 16–25, the term ''average,'' when used to describe multiple providers' costs, means an average of provider costs weighted in proportion to each provider's total minutes.) Subsequently, in a Further Notice of Proposed Rulemaking released November 3, 2015, the Commission proposed to temporarily freeze the compensation rates of providers handling 500,000 or fewer monthly minutes. *Structure and Practices of the Video Relay Services Program, Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CG Docket Nos. 10–51, 03–123, Further Notice of Proposed Rulemaking, published at 80 FR 72029, November 18, 2015, (*VRS Rate Freeze FNPRM*).

4. The Commission adopts its proposal to temporarily ''freeze'' the compensation rates of providers handling 500,000 or fewer monthly minutes (the smallest VRS providers) and directs the TRS Fund administrator to pay compensation, subject to a possible true-up, at a compensation rate of $5.29 per VRS minute for the period from July 1, 2015, to October 31, 2016.