DEPARTMENT OF SOCIAL AND HEALTH SERVICES
MEDICAID PURCHASING ADMINISTRATION
Olympia, Washington

To:	Indian Health Service Providers Tribal 638 Health Clinic Providers	**# Memo: 11-44** **Issued:** June 7, 2011
From:	Doug Porter, Administrator and Medicaid Director Health Care Authority/Medicaid Purchasing Administration	**For information, contact:** Deborah Sosa, Native Health Program Manager 360-725-1649 **Supersedes Memo #: 10-55**

Subject: **Tribal Health Program: IHS/OMB Encounter Rate Increase, and New Enrollment/Disenrollment Process Implemented**

The Department of Social and Health Services (the Department) informs Indian Health Services (IHS) and Tribal 638 Health Clinic providers of the following:

- **Retroactive to January 1, 2011**, the Department has increased the encounter rate in the IHS/Office of Management and Budget (OMB);
- **Effective for dates of service on and after July 1, 2011**, the Department will reimburse all claims at the increased encounter rate submitted during calendar year 2011.
- A mass adjustment will be made for previously paid claims from January 1, 2011 through June 30, 2011. Providers do not need to rebill claims previously paid by the Department;
- **For Calendar Year 2011**, changes to the state match for encounter; and
- **Effective immediately**, the Department implements an electronic enrollment/disenrollment process.

What has Changed?

Retroactive for claims with dates of service on and after January 1, 2011, the IHS encounter rate increased from $289.00 per encounter to $294.00 per encounter.

Effective July 1, 2011, the Department will pay the increased IHS encounter rate of $294.00 for Medicaid-covered services provided on dates of service on and after January 1, 2011.

Changes to the State Match for Non-Native Chemical Dependency Services Encounter Rate

The Federal Medical Assistance Percentages (FMAP) rate for Calendar Year 2011 (CY2011) period is:

State Fiscal Year	**CY2011**
Time Period	**July 2011-December 2011**
FMAP - State percentage	**50.00%**
FMAP - Federal percentage	**50.00%**
State Match for Encounter	**$147.00**

Effective July 1, 2011, tribes contracting to serve non-native Medicaid clients must use $147.00 to calculate the "State Match for Encounter" amount when billing for non-native Medicaid client encounter services.

Mass Adjustment for Previous Claims

A mass adjustment to pay providers the difference between the old and the new encounter rate for claims previously paid by the Department is targeted to be completed by November 30, 2011. This adjustment will affect claims for dates of service retroactive to January 1, 2011 to June 30, 2011, which the Department finalized and paid at the old encounter rate of $289.00. ***Do not rebill claims* that the Department has already paid.**

Note: If claims are made at the lower rate *after the mass adjustment started on July 1, 2011*, it is the responsibility of the provider to adjust the claim through ProviderOne.

Department Managed Care Enrollment/Disenrollment

Effective immediately, the Department processes requests made by tribal clinic providers on behalf of Medicaid clients to enroll and disenroll a client for an exemption or to take them out of managed care. Requests are processed electronically using the WEBFORM online at: http://hrsa.dshs.wa.gov/contact/default.aspx.

Instructions to Enroll/Disenroll

1. Click the above hyperlink. The ***Washington State Medicaid Customer Service*** webpage will appear.

2. Click "**Send us your questions, changes and problems!"** The ***Welcome to the ProviderOne Web Forms*** webpage will appear.

   (Follow the next step if you are using the Web Form on behalf of the client.)

3. Click the "**Client**" button. The "**Client Web Form**" will appear. Click inside the box next to "**Your Email Address:*.**" Enter your email address in the box.

4. Click on the **blue down arrow** on the right side of the box next to "**Select Topic:*.**" A drop down box will appear. Select "**Health Plans"** from the list.

5. The "**Other Comments**" box will appear at the bottom of the form. After entering all the information to enroll or disenroll a client, click the "**Submit Data**" button to send to the Medicaid Purchasing Administration to process your request.

6. A "**Thank you for contacting us**" screen will appear with a "service request number" appearing in red. **Please record the "service request number" to use as a reference.**

See page B.9 in the *Tribal Health Program Billing Instructions*.

How Can I Get the Department/MPA Provider Documents?

To download and print the Department/MPA provider numbered memos and billing instructions, go to the Department/MPA website at http://hrsa.dshs.wa.gov (click the ***Billing Instructions and Numbered Memorandum*** link).

I. Background

Various types of medical devices used in healthcare settings, from surgical suction tips to complex endoscopes, are designed and labeled for use on multiple patients. The workshop will focus on medical devices that are intended for reuse after reprocessing, rather than third-party reprocessing of single-use-only medical devices.

Thousands of reusable medical devices requiring reprocessing are used every day in diagnosing and treating patients. FDA has received a number of reports of patient exposure to inadequately reprocessed medical devices and subsequent healthcare-associated infections (HAIs). Several reports contained evidence suggesting that inadequate reprocessing may have been a contributing factor in microbial transmission and subsequent infection. A definitive causal relationship between reusable device reprocessing and any patient infection is difficult to establish, because inadequate reprocessing is not often investigated as a cause when an HAI is diagnosed. Ensuring adequate reprocessing of reusable medical devices could reduce the incidence of HAIs associated with the use of a reprocessed medical device. This will decrease the public health burden of HAIs in terms of morbidity, mortality and cost.

The adequate reprocessing of reusable medical devices is a critically important factor in protecting patient safety. Inadequate reprocessing between patients can result in the retention of blood, tissue, and other biological debris (soil) in reusable medical devices. This soil can allow microbes to survive the high level disinfection or sterilization process, potentially resulting in HAIs or other adverse patient outcomes. FDA receives reports of problems in all steps of medical device reprocessing [1], including cleaning, disinfecting and sterilizing. Manufacturers, healthcare facilities, healthcare professionals, and the FDA all have a role in reducing the risk of inadequately reprocessed medical devices.

Because of the critical importance of adequate reprocessing of medical devices, the FDA has launched an initiative to focus on improvements in device design, reprocessing procedures and validation methodologies, and healthcare facility quality assurance practices. To help address these issues, the FDA has engaged partners at the Centers for Disease Control and Prevention (CDC), the Centers for Medicaid and Medicare Services (CMS), the Veterans Health Administration (VHA), and The Joint Commission (JC), who bring valuable expertise in disease control and healthcare practices to this initiative.

[1] A more comprehensive description of reprocessing steps is available in FDA's draft guidance "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" at *http://www.fda.gov/reprocessingreusabledevices.*

II. Topics for Discussion at the Public Workshop

The public workshop will be organized to discuss the following topic areas:

1. What are the nature, scope, and impact of reusable medical device reprocessing problems that have been observed? What are the causes of these problems?
2. What factors or criteria to facilitate reprocessing should be considered when designing reusable medical devices? How can the design process be improved to better incorporate cleanability as a design endpoint?
3. What factors or criteria should be considered when developing reprocessing instructions and validation protocols for devices to be used in various healthcare environments (e.g., hospital, ambulatory surgical center, physician's office), based on the draft guidance document "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" at *http://www.fda.gov/reprocessingreusabledevices.*
4. What factors or criteria should be considered by a healthcare facility when developing reusable device reprocessing procedures and quality assurance processes?
5. How should problems with reusable medical device reprocessing be identified, reported, and acted upon by industry and users?

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857. A link to the transcripts will also be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select this public workshop from the posted events list), approximately 45 days after the public workshop.

Dated April 26, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Reimbursement Rates for Calendar Year 2011

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: Notice is given that the Director of Indian Health Service (IHS), under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*), has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for Calendar Year 2011 for Medicare and Medicaid beneficiaries and beneficiaries of other Federal programs. The Medicare Part A inpatient rates are excluded from the table below as they are paid based on the prospective payment system. Since the inpatient rates set forth below do not include all physician services and practitioner services, additional payment may be available to the extent that those services meet applicable requirements.

Inpatient Hospital Per Diem Rate (Excludes Physician/Practitioner Services)	
Calendar Year 2011	
Lower 48 States	$2,034
Alaska	2,269

Outpatient Per Visit Rate (Excluding Medicare)	
Calendar Year 2011	
Lower 48 States	294
Alaska	490

Outpatient Per Visit Rate (Medicare)	
Calendar Year 2011	
Lower 48 States	256
Alaska	447

Medicare Part B Inpatient Ancillary Per Diem Rate	
Calendar Year 2011	
Lower 48 States	443
Alaska	756

Outpatient Surgery Rate (Medicare)

Established Medicare rates for freestanding Ambulatory Surgery Centers.

Effective Date for Calendar Year 2011 Rates

Consistent with previous annual rate revisions, the Calendar Year 2011 rates will be effective for services provided on/or after January 1, 2011 to the extent consistent with payment authorities including the applicable Medicaid State plan.

Dated: March 7, 2011.

Yvette Roubideaux,

Director, Indian Health Service.

[FR Doc. 2011–10623 Filed 4–29–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

New Proposed Collection; Comment Request; Neuropsychosocial Measures Formative Research Methodology Studies for the National Children's Study

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Neuro-developmental and Psycho-Social Measures Formative Research Studies for the National Children's Study (NCS).

Type of Information Collection Request: Generic Clearance.

Need and Use of Information Collection: The Children's Health Act of 2000 (Public Law 106–310) states:

(a) PURPOSE.—It is the purpose of this section to authorize the National Institute of Child Health and Human Development* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

(b) IN GENERAL.—The Director of the National Institute of Child Health and Human Development* shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

(1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

(2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.

(c) REQUIREMENT.—The study under subsection (b) shall—

(1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;

(2) gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and

(3) consider health disparities among children, which may include the consideration of prenatal exposures.

To fulfill the requirements of the Children's Health Act, the results of formative research will be used to maximize the efficiency (measured by scientific robustness, participant and infrastructure burden, and cost) of tools to assess language, behavior, and neurodevelopment, psychosocial stress, and health literacy and thereby inform data collection methodologies for the National Children's Study (NCS) Vanguard and Main Studies. With this submission, the NCS seeks to obtain an OMB generic clearance to conduct formative research featuring neuro-developmental and psycho-social measures.

The NCS has obtained an OMB generic clearance to conduct survey and instrument design and administration, focus groups, cognitive interviews, and health and social service provider feedback information collection surrounding outreach, recruitment, and retention (0925–0590; requesting renewal). Under separate notice, the NCS is also requesting an OMB generic clearance to conduct formative research featuring biospecimen and physical measures, environmental, and study logistic information collection. These separate and distinct generic clearances are requested to facilitate the efficiency of submission and review of these projects as required by the OMB Office of Information and Regulatory Affairs.

Background

The National Children's Study is a prospective, national longitudinal study of the interaction between environment, genetics on child health and development. The Study defines "environment" broadly, taking a number of natural and man-made environmental, biological, genetic, and psychosocial factors into account. By studying children through their different phases of growth and development, researchers will be better able to understand the role these factors have on health and disease. Findings from the Study will be made available as the research progresses, making potential benefits known to the public as soon as possible. The National Children's Study is led by a consortium of federal partners: the U.S. Department of Health and Human Services (including the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences of the National Institutes of Health and the Centers for Disease Control and Prevention), and the U.S. Environmental Protection Agency.

To conduct the detailed preparation needed for a study of this size and complexity, the NCS was designed to include a preliminary pilot study known as the Vanguard Study. The purpose of the Vanguard Study is to assess the feasibility, acceptability, and cost of the recruitment strategy, study procedures, and outcome assessments that are to be used in the NCS Main Study. The Vanguard Study begins prior to the NCS Main Study and will run in parallel with the Main Study. At every phase of the NCS, the multiple methodological studies conducted during the Vanguard phase will inform the implementation and analysis plan for the Main Study.

In this submission, NCS is requesting an OMB generic clearance for formative research activities relating to the collection of neuro-developmental and psycho-social measures. The results from these formative research projects will inform the feasibility (scientific robustness), acceptability (burden to participants and study logistics) and cost of NCS Vanguard and Main Study neuro-developmental and psycho-social measures in a manner that minimizes public information collection burden compared to burden anticipated if these projects were incorporated directly into either the NCS Vanguard or Main Study.

The NCS has obtained generic clearance for formative research activities pertaining to outreach, recruitment and retention (0925–0590).