

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107–109; Pub. L. 108–155; Pub. L. 113–54.

■ 2. In § 14.100, add paragraph (d)(5) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(d) * * *

(5) *Patient Engagement Advisory Committee.*

(i) Date Established: October 6, 2015.

(ii) Function: Provides advice to the Commissioner on complex issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes, and device-related quality of life or health status issues are among the topics that may be considered by the Committee. The Committee provides relevant skills and perspectives in order to improve communication of benefits, risks, and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

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Dated: March 15, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–06240 Filed 3–18–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR**Bureau of Indian Affairs****25 CFR Part 169**

[156A2100DD/AAKC001030/
A0A501010.999900 253G]

RIN 1076–AF20

Rights-of-Way on Indian Land

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule; extension of effective date and compliance date.

SUMMARY: The Bureau of Indian Affairs (BIA) is announcing the extension of the effective date of the final rule published November 19, 2015 governing rights-of-way on Indian land, which was scheduled to take effect on December 21, 2015, and later extended to March 21, 2016. The final rule will now take effect on April 21, 2016. The BIA is also announcing an extension of the compliance date by which documentation of past assignments must be submitted from the extended date of July 17, 2016, to August 16, 2016. The final rule comprehensively updates and streamlines the process for obtaining Bureau of Indian Affairs (BIA) grants of rights-of-way on Indian land and BIA land, while supporting tribal self-determination and self-governance.

DATES: The effective date of the final rule published on November 19, 2015 (80 FR 72492) is extended until April 21, 2016. The compliance date for submission of documentation of past assignments is extended until August 16, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth Appel, Director, Office of Regulatory Affairs & Collaborative Action, (202) 273–4680; elizabeth.appel@bia.gov.

SUPPLEMENTARY INFORMATION: On November 19, 2015, BIA published a final rule addressing rights-of-way on Indian land and BIA land. *See* 80 FR 72492. In a document published December 21, 2015, BIA extended the effective date of the rule to March 21, 2016, in response to requests from tribes and industry in order to provide additional time to prepare for implementation to ensure compliance. *See* 80 FR 79258. BIA is again extending the effective date of the final rule. This document extends the effective date of the final rule to April 21, 2016, and likewise extends the deadline for providing BIA with documentation of past assignments to August 16, 2016. The substance of the rule remains

unchanged and this will be the final extension of the effective date.

The BIA has determined that the extension of the effective date and compliance date without prior public notice and comment is in the public interest because it would allow more time for the public to comply with the rule. This is a rule of agency procedure or practice that is exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

Correction

In FR Rule Doc. No. 2015–28548, published November 19, 2015, at 80 FR 72492, make the following corrections:

■ 1. On page 72537, in the center and right columns, in revised § 169.7, remove the date “December 21, 2015” wherever it appears and add in its place “April 21, 2016”.

■ 2. On page 72537, in the right column, in paragraph (d) of revised § 169.7, remove the date “April 18, 2016” and add in its place “August 16, 2016”.

Dated: March 15, 2016.

Lawrence S. Roberts,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 2016–06269 Filed 3–18–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 117**

[Docket No. USCG–2016–0183]

Drawbridge Operation Regulation; Trent River, New Bern, NC

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the US 70 (Alfred C. Cunningham) Bridge across the Trent River, mile 0.0, at New Bern, NC. The deviation is necessary to ensure the safety of attendees to the annual Mumfest celebration. This deviation allows the bridge draw span to remain in the closed to navigation position at two hour increments to accommodate the free movement of pedestrians and vehicles during the annual Mumfest celebration.

DATES: This deviation is effective from 9 a.m. on October 8, 2016 to 7 p.m. on October 9, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0183] is

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://www.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