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September 6, 2016

The Honorable Andy Slavitt, Acting Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services Attention: CMS-1656-P Mail Stop: C4-26-05 7500 Security Boulevard Baltimore, MD 21244 - 1850

RE: Medicare Program: "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs" (CMS-1656-P)

Dear Mr. Slavitt:

On behalf of the National Indian Health Board (NIHB), I write to submit comments on the proposed rule, published in the Federal Register on July 14, 2016, entitled "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program; Proposed Rule.

. Established in 1972, the NIHB is an inter-Tribal organization that advocates on behalf of Tribal governments for the provision of quality health care to all American Indians and Alaska Natives (AI/ANs). The NIHB is governed by a Board of Directors consisting of a representative from each of the twelve Indian Health Service (IHS) Areas. Each Area Health Board elects a representative to sit on the NIHB Board of Directors. In areas where there is no Area Health Board, Tribal governments choose a representative who communicates policy information and concerns of the Tribes in that area with the NIHB. Whether Tribes operate their entire health care program through contracts or compacts with IHS under Public Law 93-638, the Indian Self-Determination and Education Assistance Act (ISDEAA), or continue to also rely on IHS for delivery of some, or even most, of their health care, the NIHB is their advocate.

Background

In this proposed rule, CMS describes proposes to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) beginning January 1, 2017. A section of the rule

implements section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74). This provision requires that certain items and services furnished in certain off-campus provider-based departments (PBDs) (collectively referenced as non-excepted items and services) shall not be considered covered OPD services for purposes of OPPS payment and those items and services will instead be paid "under the applicable payment system" beginning January 1, 2017.

CMS proposes a number of changes relating to which off-campus PBDs and which items and services furnished by such off-campus PBDs may be exempt from application of payment changes under this provision. CMS explains the recent trend of hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resultant increase in the delivery of physician's services in a hospital setting results in higher Medicare payments than the total payment amount made by Medicare when the beneficiary receives those same services in a physician's office.

CMS explains that Medicare pays a higher amount because it generally pays two separate claims for these services—one under the OPPS for the institutional services and one under the MPFS for the professional services furnished by a physician or other practitioner. Medicare beneficiaries are responsible for the cost-sharing liability, if any, for both of these claims, often resulting in significantly higher total beneficiary cost-sharing than if the service had been furnished in a physician's office. NIHB provides comments on this aspect of the proposed rule below.

Proposed Nonrecurring Policy Changes

A. Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider

Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, amended section 1833(t) of the Act. Specifically, this provision amended the OPPS statute at section 1833(t) by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under section 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, will not be considered covered OPD services as defined under section 1833(t)(1)(B) for purposes of payment under the OPPS and will instead be paid "under the applicable payment system" under Medicare Part B if the requirements for such payment are otherwise met. We note that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65.

It is important to note that that the CMS Tribal Technical Advisory Group (TTAG) has provided previous comments regarding the Medicare provider-based status of Indian Health Service (IHS) and Indian Tribal Health Programs and the criteria established under 42 CFR 413.65. To reiterate some of the important points of the TTAG comments is that the federal policy of self-determination is founded on the idea that Tribes and tribal organizations do better

¹ See CMS-TTAG Letter to Marck Hartstein, Director, Hopspital and Ambulatory Policy Group, dated July 9, 2015.

at providing services for themselves than the federal government. A key element of this process is that a tribal organization's ability to take over these programs is dependent on its ability to collect third-party revenue for services provided. If a tribal organization loses access to third-party revenues the level of services it can provide is significantly reduced, which may cause these organizations to forego contracting at all.

A key element of the proposed regulation has to do with the defining the term "off-campus outpatient department of a provider," section 1833(t)(21)(B)(i) of the Act specifies that the term means a department of a provider that is not located on the campus of such provider, or within the distance from a remote location of a hospital facility. Section 1833(t)(21)(B)(ii) of the Act excepts from the definition of "off-campus outpatient department of a provider," for purposes of paragraphs (1)(B)(v) and (21)(B), an off-campus PBD that was billing under subsection (t) with respect to covered OPD services furnished prior to the date of enactment of paragraph (t)(21), that is, November 2, 2015. CMS refers to this exception as providing "excepted" status to certain off-campus PBDs and certain items and services furnished by such excepted off-campus PBDs, which would continue to be paid under the OPPS.

The proposed rule describes changes to the amounts and factors used to determine the payment rates for Medicare services paid under OPPS and those paid under the ASC payment system. This provision requires that, beginning January 1, 2017, payment for certain items and services furnished in certain off-campus provider-based departments (PBDs) (collectively referenced as non-excepted items and services) shall occur "under the applicable payment system." This proposed rule includes several policies relating to which off-campus PBDs and which items and services furnished by such off-campus PBDs application of payment changes under this provision might not apply. In addition, under this proposed rule the Medicare Physician Fee Schedule (MPFS) would serve as the "applicable payment system" for the majority of the items and services furnished by non-excepted off-campus PBDs.

As you know, Indian health providers are not subject to the OPPS and therefore, this rule should not apply. Even though the rule discusses off-campus provider based facilities, and restrictions on relocation, an Indian health care facility that has grandfathered provider based status covered at 42 CFR 413.65(m) has no restrictions when it comes to replacing the facility. The provider based status is continuous and therefore there are no changes with the new facility, even if there is an expansion of services. The regulation at 42 CFR 413.65(m) establishes a special "grandfather" provision for certain IHs and Tribal facilities. Under that provision, clinics and other facilities that do not meet provider-based criteria but were billing as components of IHS or Tribal hospitals when the regulations were first published in final form (on April 7, 2000) may continue to be treated as provider-based.²

It is our understanding that CMS is taking a very narrow interpretation of 42 CFR 413.65(m) and its interpretation of this proposed rule where off campus outpatient facilities may

² See CMS letter from Thomas Grissom, Director, Center for Medicare Management, to Marti Mahaffey, Executive Vice-President, Trailblazer Health Enterprises, dated August 11, 2003.

apply to the Indian health system. Therefore we recommend that CMS ensure that grandfathered status remains intact and is clearly referenced for Tribes as well as IHS in the final rule.

We fail to understand the benefit of applying this policy to a federally-funded health system that the United States has a federal trust responsibility to provide health care services to Alaska Native and American Indians. This federal trust responsibility alone is justification for exempting the Indian health care system from the provider based rule. This narrow interpretation by CMS has far reaching and potentially devastating impact across the already underfunded Indian health care system.

Conclusion

NIHB respectfully requests that CMS further consult with the CMS Tribal Technical Advisory Group and Tribes if the result of CMS actions in the final regulation will negatively affect the provider-based status of current programs or the opportunity of tribal health programs that may enter into agreements in the future with the Indian Health Service ("IHS") under the Indian Self-Determination and Education Assistance Act, Pub. L. 93-638, as amended ("ISDEAA"). We thank you for this opportunity to provide our comments and recommendations and look forward to further engagement with CMS on this important proposed rule. Please contact NIHB's Director of Federal Relations at ddelrow@nihb.org or (202) 507-4072 if there are any additional questions or comments on the issues addressed in these comments.

Sincerely,

Lester Secatero

Chairman, National Indian Health Board

Cc: Kitty Marx, Director, CMS Division of Tribal Affair Mary Smith, Principal Deputy Director, Indian Health Service