All Tribes Consultation Webinar on Indian Health Services Payment for High-Cost Drugs

July 25, 2024

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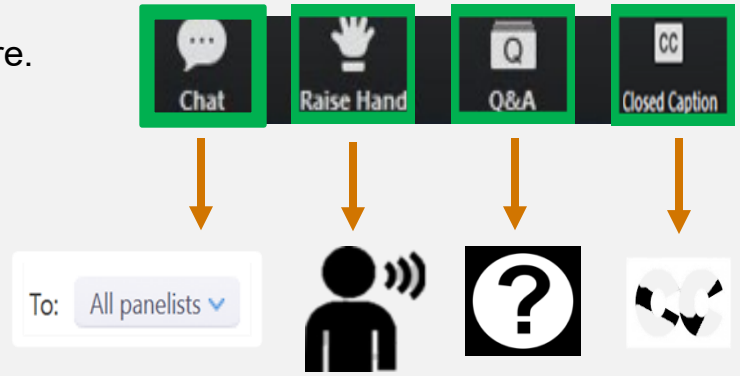

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Hospital and Ambulatory Policy Group,
Center for Medicare

July 25, 2025

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Agenda and Attendees

Today's Agenda

- Current IHS Payment Policy
- Background
- 2025 High-Cost Drug Proposal in OPPS Rule
  - Proposed Payment Methodology
  - Proposed Threshold
  - Proposed Qualifying Drugs
  - Proposed Payment Amount
  - Proposed Implementation
  - Additional Drug Comment Solicitations
- Request for Information-IHS AIR

Center for Medicare Attendees

- David Rice
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Summary of Drug Policy

- 2024 OPPS/ASC rulemaking - solicited comment on additional payment approaches to provide equitable payment for high-cost drugs and services provided by IHS and tribal hospitals.

- 2025 OPPS/ASC proposed rule – propose to separately pay IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through an add-on payment to the All Inclusive Rate (AIR).

Current Payment Policy

- Under current regulations, IHS and tribal hospitals are excluded from payment under the OPPS.
- IHS and tribal outpatient departments are paid the Medicare outpatient hospital AIR for each encounter that provides outpatient services.
- On an annual basis, the IHS calculates and publishes calendar year reimbursement rates.
- For CY 2024, the outpatient AIR is $667 in the lower 48 states and $961 for Alaska.

Background

- IHS and tribal hospitals have continued to expand the breadth of services that they provide. Consequently, there are hospitals providing specialty services where the AIR might not be an adequate representation of the hospital's costs to provide services to people with Medicare.
- This could be a significant equity and beneficiary access concern if IHS and tribal hospitals are not able to provide high-cost drugs to the populations they serve.

2025 High-Cost Drug Proposal

- Propose to establish an add-on payment to the AIR for high-cost drugs in outpatient departments of IHS/tribal hospitals.
- Proposed policy is intended to provide equitable payment for high-cost drugs.
- We anticipate that this policy would enable IHS and tribal hospitals to provide specialty services that require high-cost drugs to a historically underserved population.

Proposed AIR Add-On Payment Methodology

- IHS/Tribal Hospitals would receive the AIR payment, plus an add-on payment for qualifying drugs.

- The proposed add-on payment would have no effect on the calculation of the annual AIR payment amounts.

Proposed Qualifying Threshold

- To receive the additional payment, qualifying drugs must exceed the threshold of two times the lower 48 AIR ($1,334).

- This threshold would ensure that the add-on payment would apply only to drugs whose costs significantly exceed the AIR.

Proposed Qualifying Drugs

- Includes all high-cost drugs furnished in hospital outpatient departments of IHS and tribal hospitals that are:
  1. Drugs covered under Medicare Part B
  2. Would be paid for under the OPPS if furnished by an OPPS hospital
  3. Cost of the drug excesses two times the lower 48 AIR for 2025
- Addendum Q[1] of the 2025 OPPS/ASC proposed rule lists of 325 qualifying drugs using two times the CY 2024 lower 48 AIR ($1,334) as the cost threshold.

1 https://www.cms.gov/license/ama?file=/files/zip/2025-nprm-opps-addenda.zip

Proposed Add-On Payment Amount

- Propose to price the additional payment amount for each qualifying drug at the Average Sales Price (ASP).

- Consistent with OPPS payment for most drugs, which uses the ASP methodology (ASP + 6 percent), but recognizes that IHS and tribal facilities primarily obtain their drugs through the Federal Supply Schedule, with rates significantly lower than ASP

- When ASP information is not available for a drug, we proposed payment at:
  - Wholesale Acquisition Cost (WAC). If unavailable;
  - 89.6 percent of Average Wholesale Price (AWP).

Proposed Implementation

- Annual announcement in the Federal Register in December 2024 includes the lower 48 AIR amount for 2025. CMS would multiply the lower 48 AIR amount by the finalized threshold multiplier, and then compare to costs of drugs.

- A list of drugs whose costs exceed the final threshold would be communicated to IHS and tribal hospitals prior to January 1, 2025. The list of drugs would be updated on a quarterly basis.

- During 2025, hospitals would submit claims for drugs on this list.

- This process would be repeated on an annual basis.

Additional High-Cost Drug Policy Comment Solicitations

- We seek comment on:
  - Setting the payment threshold at 1.75 times the lower 48 AIR to align it with the multiplier used to calculate outlier payments under the OPPS.
  - Add-on payment for biosimilars whose per-day costs do not exceed the threshold but whose reference products do exceed the threshold.
  - Paying ASP plus 6 percent for qualifying drugs above the threshold.
- Comments on this proposed rule must be submitted to Regulations.gov before comment due date on September 9th.[2]

2 https://www.regulations.gov/document/CMS-2024-0199-0001.

Request for Information (RFI)

Paying all IHS and Tribally Operated Clinics the IHS Medicare Outpatient All Inclusive Rate

Request for Information (RFI)

Background:

- June 2020 TTAG Letter
- CY 2022 PFS NPRM Comment Solicitation
- Fall 2023 Workgroup
- RFI in CY 2025 OPPS NPRM

Request for Information (RFI)

The following information will be helpful:

- Equity and/or access concerns
- The types of clinics/facilities
  - Physician Offices/Practices
  - FQHCs
  - Provider Based or Freestanding
  - Other clinic type

Request for Information (RFI)

- Enrollment & Billing
  - Are the clinics enrolled in Medicare?
  - Do the clinics bill the Physician Fee Schedule, Medicare FQHC PPS, other Medicare payment system?
  - Would clinics enroll as Medicare FQHCs?
- Clinic Costs
  - Evidence that supports IHS outpatient AIR for all clinics

Questions?

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