

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12727	Date: July 18, 2024
	Change Request 13698

NOTE: This Transmittal is no longer sensitive and is being re-communicated November 06, 2024. The Transmittal Number, date of Transmittal and all other information remains the same. This instruction may now be posted to the Internet.

SUBJECT: All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service (IHS) and Tribal Hospitals

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to implement the changes that are necessary to make an add-on payment for high-cost drugs provided by IHS and tribal hospitals in addition to the All-Inclusive Rate (AIR), effective January 1, 2025.

EFFECTIVE DATE: January 1, 2025

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 6, 2025

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	N/A

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

One Time Notification

Attachment - One-Time Notification

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II. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to implement the changes that are necessary to make an add-on payment for high-cost drugs provided by IHS and tribal hospitals in addition to the All-Inclusive Rate (AIR), effective January 1, 2025.

B. Policy: IHS and tribal facilities are paid for items and services furnished in hospital outpatient departments on an encounter basis under the AIR, which is a separate payment system from the OPSS. On an annual basis, the IHS calculates and publishes, in the Federal Register, the AIR for a calendar year based on cost report data.[1] Due to the higher cost of living in Alaska, separate rates are calculated for Alaska and the lower 48 states. For CY 2024, the Medicare Outpatient per Visit Rate is \$667 for the lower 48 states and \$961 for Alaska.[2]

In the CY 2025 OPSS/ASC proposed rule, CMS is proposing to pay IHS and tribal hospitals, for high-cost drugs furnished in hospital outpatient departments through the establishment of an add-on payment to the AIR under Sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248), Public Law 83-568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.), which are the authorities under which the annual (AIR) is calculated.

CMS is proposing to define a high-cost drug as any drug covered under Medicare Part B and payable under the OPSS whose per-day cost exceeds two times the annual lower 48 states' AIR (\$1,334 in CY 2024). For drugs exceeding this two times threshold, CMS is proposing to pay the Average Sales Price (ASP + 0%) for the drug. Thus, CMS proposes that for an encounter featuring one or more high-cost drugs, the hospital would receive the AIR payment for the encounter (\$667 in CY 2024) plus an add-on payment (ASP + 0%) for the high-cost drug(s).[3] CMS will provide the CY 2025 payment amounts for drugs with per-day costs that exceed the threshold in the January 2025 quarterly update to the hospital outpatient prospective payment system transmittal.

To implement this proposed policy, CMS is proposing that, starting with IHS's annual announcement in the Federal Register in December 2024 of the lower 48 AIR amount for CY 2025, CMS would multiply the lower

48 AIR amount by two and then compare the result to the estimated per day costs of all drugs covered under Part B and payable under the OPSS. A list of drugs whose costs exceeds two times the lower 48 AIR would be generated and communicated to IHS and tribal hospitals prior to January 1, 2025. During CY 2025, IHS and tribal hospitals would submit claims for drugs present on this list with the list being updated on a quarterly basis using existing drug compendia and CMS ASP quarterly reporting to account for newly introduced drugs and changes in drug prices. These drugs would be paid for in addition to the AIR using AIR authorities, and not the OPSS, from which IHS and tribal hospitals are excluded. CMS would then repeat this process on an annual basis each December when the lower 48 AIR amount for the following calendar year is announced by IHS. CMS would transmit the list of drugs with per-day costs that exceed two times the lower 48 AIR and thus, eligible for the AIR add-on payment to the IHS and tribal MAC (Novitas) in the January 2025 quarterly update to the hospital outpatient prospective payment system transmittal and provide an updated list quarterly as applicable.

The policies described in this CR are based on proposed policies in the CY 2025 OPSS/ASC proposed rule. All policies described in this CR are subject to change pending the publication of the final policies adopted in the CY 2025 OPSS/ASC Final Rule. If there are changes to these proposed policies in the CY 2025 Final Rule, such as changes made in response to public comments, CMS will provide further instruction.

[1] <https://www.ihs.gov/BusinessOffice/reimbursement-rates/>

[2] <https://www.federalregister.gov/documents/2023/12/19/2023-27815/reimbursement-rates-for-calendar-year-2024>

[3] IHS Critical Access Hospitals (CAHs) are paid for covered outpatient services based on 101 percent of an all-inclusive facility specific rate rather than the national AIR rate. Consequently, they are excluded from the proposed separate payment policy and this change request.

III. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
13698.1	Effective January 1, 2025, the Shared-System Maintainer shall accept and process Type of Bills (TOBs) 012X and 013X claims for certain high-cost drugs through an add-on payment to the All-Inclusive Rate (AIR) for IHS/Tribal facilities with a provider type 08. NOTE: IHS/Tribal Facilities provider type 08. IHS/Tribal CAH Facilities provider type 37.					X					
13698.1.1	The Shared-System Maintainers shall accept and process payment on TOBs 012X or 013X for					X					

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared-System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
	IHS/Tribal facilities with a provider type 08 containing Revenue Code 0636 and use the Record B rate from the ASP drug file for IHS/Tribal facilities payment. Note: Coinsurance and/or deductible will be applied to the 0636 revenue code line. In addition, the Medicare Summary Notice (MSN) should continue to be suppressed.										
13698.2	The Shared-System Maintainers shall create a new Reason Code edit to return-to-provider (RTP) claims for TOBs 012X or 013X for IHS/Tribal facilities with a provider type 08 containing Revenue Code 0636 and the HCPCS code has no rate on the Record B from the ASP drug file for the quarter in which the Line Item Date of Service (LIDOS) on the claim line falls. NOTE: The IHS providers are paid by the A/B MAC (A) for covered drugs and biologicals, that are not considered for add-on to the AIR, provided during a clinic visit. All charges, except those that are considered for add-on to the AIR, are combined and reported under revenue code 0510 (clinic visit) on TOB 13X (IHS/tribal hospitals and hospital-based clinics).	X				X					

IV. PROVIDER EDUCATION

None

Impacted Contractors: None

V. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
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Section B: All other recommendations and supporting information:N/A

VI. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VII. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

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ATTACHMENTS: 0