CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12511	**Date: February 15, 2024**
	Change Request 13504

SUBJECT: Manual Updates to Chapters 1 and 17 of the Medicare Claims Processing Manual to Reflect Policies Finalized in the Calendar Year (CY) 2024 Physician Fee Schedule Final Rule

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to make revisions to Chapters 1 and 17 of the Medicare Claims Processing Manual (Publication 100-04) to reflect policies finalized in the calendar year (CY) 2024 Physician Fee Schedule final rule:

- In Chapter 1, section 30.3.3, we are adding a cross-reference to Chapter 20, regarding the monthly coinsurance limitations on insulin furnished through a covered item of DME, as required by section 11407 of the Inflation Reduction Act. In the CY 2024 Physician Fee Schedule final rule, we codified corresponding regulations in new paragraph (b)(7) at § 489.30 and new paragraph (n) at § 410.152.

- In Chapter 17, Table of Contents, we are adding a new line item for section 10.1 - Payment Rules for Drugs and Biologicals Subject to the Inflation-Adjusted Coinsurance Policy.

- In Chapter 17, we are adding new section 10.1 to reflect payment rules for rebatable drugs, as required by section 11101 of the Inflation Reduction Act. In the CY 2024 Physician Fee Schedule final rule, we codified corresponding regulations at § 489.30 and § 410.152.

- In Chapter 17, section 20.1.2, we are incorporating payment rules for qualifying biosimilar biological products, as required by section 11403 of the Inflation Reduction Act, as well as updating references to the term "payment limits" (formerly "payment allowance limits). In the CY 2024 Physician Fee Schedule final rule, we codified corresponding regulations at § 414.902 and new paragraphs (j)(1) and (2) at § 414.904(j).

- In Chapter 17, section 20.1.3, we are incorporating the new payment rules for biosimilar biological products in their initial period, as required by section 11402 of the Inflation Reduction Act, as well as updating references to the term "payment limits" (formerly "payment allowance limits"). In the CY 2024 Physician Fee Schedule final rule, we codified corresponding regulations in new paragraphs (A) and (B) at § 414.904(e)(4)(ii).

- In Chapter 17, section 40, we are incorporating JW and JZ modifier reporting requirement updates made in the CY 2024 Physician Fee Schedule final rule that continue to implement section 90004 of the Infrastructure and Investment Act, including that beginning January 1, 2024, suppliers who do not administer the drug must bill separately payable drugs under Part B from single-dose containers with the JZ modifier. We are also clarifying that the use of the JZ modifier policy does not require that the claim line with the JZ modifier account for only whole vials of the drug and the JW modifier policy does not require that the two claim lines account for only whole vials of the drug. These

changes were made through rulemaking but there were no corresponding changes to the code of regulations.

EFFECTIVE DATE: January 1, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: March 18, 2024

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
R	1/30.3.3/Physician's Right to Collect From Enrollee on Assigned Claim Submitted to Carriers
R	17/Table of Contents
N	17/10.1/Payment Rules for Drugs and Biologicals Subject to the Inflation-Adjusted Coinsurance Policy
R	17/20.1.2/Average Sales Price (ASP) Payment Methodology
R	17/20.1.3/Exceptions to Average Sales Price (ASP) Payment Methodology
R	17/40/Discarded Drugs and Biologicals

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:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 12511	Date: February 15, 2024	Change Request: 13504

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EFFECTIVE DATE: January 1, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: March 18, 2024

I. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to make revisions to Chapters 1 and 17 of the Medicare Claims Processing Manual (Publication 100-04) to reflect policies finalized in the calendar year (CY) 2024 Physician Fee Schedule final rule.

B. Policy: No new policy. The CR updates the manual to more accurately reflect current policy.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13504.1	Contractors shall be aware of the manual updates in Pub. 100-04, Chapter 1, section 30.3.3 and Chapter 17, sections 10.1, 20.1.2, 20.1.3, and 40.	X	X		X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

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

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

Chapter 17 - Drugs and Biologicals

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- *10.1 - Payment Rules for Drugs and Biologicals Subject to the Inflation-Adjusted Coinsurance Policy*

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10.1 - Payment Rules for Drugs and Biologicals Subject to the Inflation-Adjusted Coinsurance Policy

(Rev.12511; Issued:02-15-24; Effective: 01-01-24; Implementation: 03-18-24)

For calendar quarters starting April 1, 2023, if the payment amount for a rebatable drug specified in section 1847A(i)(3)(A)(ii)(I) of the Act exceeds the inflation-adjusted payment amount, two payment adjustments are necessary. First, beneficiary coinsurance for a Part B rebatable drug is to be 20 percent of the inflation-adjusted payment amount if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount. A/B MACs should find the applicable coinsurance amount for a rebatable drug in the ASP pricing file where the coinsurance is expressed as a percent of the Medicare payment amount. If adjusted beneficiary coinsurance does not apply, the percentage is 20 percent.

Second, Medicare Part B pays, subject to the deductible and sequestration, the difference between the allowed payment amount determined under section 1847A of the Act and 20 percent of the inflation-adjusted amount. In other words, the Part B payment for a rebatable drug with an inflation-adjusted coinsurance will be greater than 80 percent of the payment amount.

20.1.2 - Average Sales Price (ASP) Payment Methodology

(Rev.12511; Issued:02-15-24; Effective: 01-01-24; Implementation: 03-18-24)

Section 303(c) of the Medicare Modernization Act of 2003 (MMA) revised the payment methodology for Part B covered drugs and biologicals that are not priced on a cost or prospective payment basis. Per the MMA, beginning January 1, 2005, the vast majority of drugs and biologicals not priced on a cost or prospective payment basis will be priced based on the average sales price (ASP) methodology. Pricing for compounded drugs is performed by the *A/B MAC and DME MAC*. Beginning in July 2015, claims for compounded drugs shall be submitted using a compounded drug, not otherwise classified (NOC) HCPCS code. Beginning in 2006, all ESRD drugs furnished by both independent and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the Outpatient Prospective Payment System (OPPS), will be priced based on the ASP methodology. The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply *MACs* with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis. *MACs* will be notified of the availability of this file via a Recurring Update Notification. Visit *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price* for more information about the ASP payment methodology.

The absence or presence of a HCPCS code and its associated payment limit does not indicate Medicare coverage of the drug or biological. Similarly, the inclusion of a payment limit within a specific column does not indicate Medicare coverage of the drug in that specific category. The *A/B MAC or DME MAC* processing the claim shall make these determinations.

Beginning January 1, 2005, in general, the payment limits for Medicare Part B drugs and biologicals that are not paid on a cost or prospective payment basis are 106 percent of the ASP. Beginning January 1, 2006, in general, the payment limits for ESRD drugs when separately billed by freestanding and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the OPPS, will be paid based on 106 percent of the ASP. CMS will update the payment limits quarterly.

In general, the payment limit for biosimilar biological products (hereafter, biosimilars) is the sum of (1) the ASP of the biosimilar and (2) 6 percent of the of the lesser of the WAC or ASP of the reference biological. For biosimilars that have an ASP less than the ASP of their reference biological during a calendar quarter during the applicable period, also known as a qualifying biosimilar biological product, that are furnished during the applicable 5-year period, the payment limit is the sum of (1) the ASP of the biosimilar and (2) 8 percent of the of the lesser of the WAC or ASP of its reference biological. For biosimilars for which payment has been made under Part B as of September 30, 2022, the applicable period is the 5-year period beginning on October 1, 2022; for those for which payment is first made under Part B between October 1, 2022 and ending December 31, 2027, the applicable period is the 5-year period beginning on the first day of the calendar quarter in which the first Part B payment is made.

As announced in late 2006, CMS has been working further to ensure that accurate and separate payment is made for single source drugs and biologicals as required by Section 1847A of the Social Security Act. As part of this effort, we have also reviewed how we have operationalized the terms "single source drug," "multiple source drug," and "biological product" in the context of payment under Section 1847A. For the purposes of identifying "single source drugs" and "biological products" subject to payment under Section 1847A, generally CMS (and *MACs*) will utilize a multi-step process. We will consider:

- The FDA approval;
- Therapeutic equivalents as determined by the FDA; and
- The date of first sale in the United States.

For a biological product (as evidenced by a new FDA Biologic License Application or other relevant FDA approval) or a single source drug (that is, not a drug for which there are two or more drug products that are rated as therapeutically equivalent in the most recent FDA Orange Book) first sold in the United States after October 1, 2003, the payment limit for a biological product or single source drug will be based on the pricing information for products marketed or sold under the applicable FDA approval. As appropriate, a unique HCPCS code *is* assigned to facilitate separate payment. Separate payment may be operationalized through use of "not otherwise classified" HCPCS codes.

20.1.3 - Exceptions to Average Sales Price (ASP) Payment Methodology

(Rev.12511; Issued:02-15-24; Effective: 01-01-24; Implementation: 03-18-24)

The payment limits for blood and blood products (other than blood clotting factors) that are not paid on a reasonable charge or prospective payment basis, are determined in the same manner the payment limits were determined on October 1, 2003. Specifically, the payment limits for blood and blood products are 95 percent of the average wholesale price (AWP) as reflected in the published compendia. The payment limits will be updated on a quarterly basis. Blood and blood products furnished in the hospital outpatient department are paid under OPPS at the amount specified for the Ambulatory Payment Classification (APC) to which the product is assigned.

The payment limits for infusion drugs furnished through a covered item of durable medical equipment furnished on or after January 1, 2005, and before January 1, 2017, is 95 percent of the AWP reflected in the published compendia as of October 1, 2003, unless the drug is compounded or the drug is furnished incident to a professional service. The payment limits for infusion drugs furnished through a covered item of durable medical equipment before January 1, 2017 that were not listed in the published compendia as of October 1, 2003, (i.e., new drugs) are 95 percent of the first published AWP unless the drug is compounded or the drug is furnished incident to a professional service. Payment for infusion drugs furnished through a covered item of durable medical equipment furnished on or after January 1, 2017 is based on ASP (or other applicable methodology in Sections 1847, 1847A, 1847B or 1881(b)(13) of the Social Security Act).

The payment limits for influenza, Pneumococcal and Hepatitis B vaccines are 95 percent of the AWP as reflected in the published compendia except where the vaccine is furnished in a hospital outpatient department. Where the vaccine is administered in the hospital outpatient department, the vaccine is paid at reasonable cost. CMS will supply *A/B MACs* with the payment limits annually to be effective on August 1 of each year. *A/B MACs* will be notified of the availability of payment limits via a Recurring Update Notification.

The payment limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based either on the published Wholesale Acquisition Cost (WAC) or invoice pricing, except under OPPS where the payment limit is 95 percent of the published AWP. In determining the payment limit based on WAC, the *A/B MACs* follow the methodology specified in Publication. 100-04, Chapter 17, Section 20.4 Drugs and Biologicals, for calculating the AWP, but substitute WAC for AWP. The payment limit is 106 percent of the lesser of the lowest-priced brand or median generic WAC.

The payment limits for new drugs and biologicals that are produced or distributed under a new drug application (or other new application) approved by the Food and Drug Administration, that are first sold on or after January 1, 2005, and that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, are based on either *(1)* the WAC as determined in the preceding paragraph, or *(2)* invoice pricing. For claims with dates of service before January 1, 2019, the add-on percentage for these WAC-based payments is 6 percent. For claims with dates of service on or after January 1, 2019, the add-on percentage for

WAC-based payments determined by MACs for new drugs before an ASP-based payment limit is available is up to 3 percent. However, in OPPS, the payment limit for new drugs and biologicals is 95 percent of the published AWP. *For claims for biosimilars with dates of service on or after July 1, 2024, the payment limit for the biosimilar is the lesser of (1) an amount not to exceed 103 percent of the WAC of the biosimilar or the Medicare Part B drug payment methodology in effect on November 1, 2003, or (2) 106 percent of the lesser of the WAC or ASP of the reference biological, or in the case of a selected drug during a price applicability period, 106 percent of the maximum fair price of the reference biological.*

The payment limits for radiopharmaceuticals are not subject to ASP. A/B MACs (B) should determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003 in the case of radiopharmaceuticals furnished in other than the hospital outpatient department. Refer to Chapter 17, §90.2 of the manual regarding radiopharmaceuticals furnished in the hospital outpatient department.

MACs shall develop payment limits for covered drugs when CMS does not supply the payment limit on the ASP drug pricing files (including the Not Otherwise Classified (NOC) Pricing file). At the *A/B or DME MAC's* discretion, a *MAC* should contact CMS to request payment limits for drugs not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS Web site. If the payment limit is available from CMS, *MACs* shall substitute CMS-provided payment limits for pricing based on WAC, invoice or other applicable pricing methodology. CMS will provide the payment limits directly to the requesting *MAC* and/or via posting on the CMS Web site.

40 - Discarded Drugs and Biologicals

(Rev.12511; Issued:02-15-24; Effective: 01-01-24; Implementation: 03-18-24)

The CMS encourages physicians, hospitals and other providers and suppliers to care for and administer drugs and biologicals to patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner.

When a billing provider or supplier must discard the remainder of a single-dose container or single-use package after administering a dose to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label.

Effective January 1, 2017, when processing claims for drugs and biologicals *A/B MACs* shall require the use of the JW modifier to identify unused and discarded amounts (hereafter, discarded amounts) of drugs or biologicals from single-dose containers or single-use packages.

The discarded amount is any amount that is not part of the prescribed dose and not intended to have a therapeutic effect in the patient. Even if certain amounts are extracted from the vial or are required to be in the vial to administer the prescribed dose, we do not consider them to be used if they are not intended for therapeutic effect as part of the prescribed dose. Generally, the discarded amount is the labeled amount on the single-dose container (or containers if more than one is required) minus the dose (the dose being the prescribed amount of drug administered to the patient).

The JW modifier, billed on a separate line, provides payment for the amount of discarded drug or biological. For the administered amount, one claim line shall include the billing and payment code (such as a HCPCS code) describing the given drug, no modifier, and the number of units administered in the unit field. For the discarded amount, a second claim line shall include the same billing and payment code as used for the administered amount, the JW modifier, and the number of units discarded in the unit's field.

For example, if a provider or supplier uses a single-dose container that is labeled to contain 100 units of a drug to administer 95 units to the patient and 5 units are discarded. The 95-unit dose is billed on one line, while the discarded 5 units shall be billed on another line with the JW modifier. Both line items would be processed for payment. Providers must record the discarded amounts of drugs and biologicals in the patient's medical record.

Effective July 1, 2023, *A/B MACs and DME MACs* shall require the use of the *JZ* modifier to attest that there are no amounts of drugs or biologicals from single-dose containers or single-use packages were unused and discarded *for which the JW modifier would be required if there were discarded amounts*. For the administered amount, the claim line should include the billing and

payment code (such as HCPCS code) describing the given drug, the JZ modifier (attesting that there were no discarded amounts), and the number of units administered in the unit's field.

The JW modifier is only applied to the amount of drug or biological that is discarded. A situation in which the JW modifier is not permitted is when the actual dose of the drug or biological administered is less than the billing unit. For example, one billing unit for a drug is equal to 10mg of the drug in a single use vial. A 7mg dose is administered to a patient while 3mg of the remaining drug is discarded. The 7mg dose is billed using one billing unit that represents 10mg on a single line item. The single line item of 1 unit would be processed for payment of the total 10mg of drug administered and discarded. Billing another unit on a separate line item with the JW modifier for the discarded 3mg of drug is not permitted because it would result in overpayment. Therefore, when the billing unit is equal to or greater than the total actual dose and the amount discarded, the use of the JW modifier is not permitted. For dates of service beginning July 1, 2023, the JZ modifier shall be used in this circumstance. *The JZ modifier policy does not require that the claim line with the JZ modifier account for only whole vials of the drug and the JW modifier policy does not require that the two claim lines account for only whole vials of the drug.*

In general, the JW and JZ modifier policy applies to all drugs separately payable under Medicare Part B that are described as being supplied in a "single-dose" container or "single-use" package based on FDA-approved labeling*, including all claims of non-refundable, single-dose container drugs such as multiple source drugs and contrast agents. However, the* use of these modifiers is not appropriate for drugs that are from multiple-dose containers. The JW and JZ modifier policy does not apply for drugs that are not separately payable, such as packaged OPPS or ASC drugs, or drugs administered in the FQHC or RHC setting.

Beginning January 1, 2024, a billing supplier who does not administer the drug must bill separately payable drugs under Part B from single-dose containers with the JZ modifier.

The JW and JZ modifiers are not required for vaccines described under section 1861(s)(10) of the Act that are furnished from single-dose containers. Since the influenza, pneumococcal, and COVID–19 vaccines specified in section 1861(s)(10) of the Act are often roster billed by mass immunizers, and roster billing cannot accommodate modifiers, it would be impractical to require the JW and JZ modifiers for such vaccines. Such a requirement would likely result in substantial operational issues for mass immunizers and impair patient access to these vaccines.

The JW Modifier and JZ Modifier Policy Frequently Asked Questions (FAQ) document addressing the correct use of these modifiers is available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf

The JW modifier is not used on claims for CAP drugs. For CAP drugs, see subsection 100.2.9 - Submission of Claims With the Modifier JW, "Drug or Biological Amount Discarded/Not Administered to Any Patient", for additional discussion of the discarded remainder of a vial or

other packaged drug or biological in the CAP. Note that the CAP is postponed effective January 1, 2009.

Chapter 1 - General Billing Requirements

30.3.3 - Physician's Right to Collect From Enrollee on Assigned Claim Submitted to Carriers

(Rev.12511; Issued:02-15-24; Effective: 01-01-24; Implementation: 03-18-24)

A. Before the Claim is Submitted

The provider (including physicians and suppliers) who is accepting assignment should not attempt to collect more than 20 percent of the charge from the enrollee when the deductible has been met. He or she should, if the occasion arises, be advised not to do so. Any greater amount collected will:

1. Reduce the amount payable to him/her on the assigned claim,

2. Cause the enrollee unnecessary hardship in raising the excess amount, and

3. Require extra work for the carrier in paying this excess to the enrollee instead of the physician.

However, a provider (including physicians and suppliers) may accept assignment after having collected a part of his/her bill. The fact that the enrollee has paid more than any deductible and coinsurance due does not invalidate the assignment.

B. Showing the Amount Collected on the Claims Form

In submitting an assigned claim, the provider (including physicians and suppliers) must show on Form CMS-1500 any amount he/she has collected from the enrollee for these services. This information is essential for correct payment of the benefits due; failure to show the amount paid is likely to result in excessive benefit payment to the provider (including physicians and suppliers) (i.e., a benefit payment which, when added to the amount already paid by the enrollee, will exceed the Medicare allowed amount).

EXAMPLE: The physician accepted assignment of a bill of $300 for covered services and collected $60 from the enrollee, but failed to show on the claim form that he/she had collected anything. The carrier determined the Medicare allowed amount to be $250, and since the deductible had previously been met, made payment of $200 to the physician. Since the physician would have received $190 in benefit payments and the enrollee $10 if the amount collected had been shown on the claim form, the physician has been overpaid $10. When this overpayment comes to light, e.g., by a complaint from the enrollee, the carrier will take necessary corrective action, e.g., advise the physician to refund the $10 to the enrollee and if he/she fails to do so, pay the enrollee the $10 and recover the overpayment from the physician.

C. Physician Should Not Bill Enrollee After the Claim is Submitted

After the provider (including physicians and suppliers) has accepted assignment he/she should not bill the enrollee or try to collect from him/her any additional part of the bill until he/she receives the carrier's Medicare Summary Notice (MSN). Where the provider (including physicians and suppliers) collects any substantial part of his/her bill from the enrollee **after** submitting his/her claim, such collection is likely to be an overcollection, and a violation of the assignment agreement. Furthermore, the enrollee who receives a bill from the provider (including physicians and suppliers) may submit such bill to the carrier with his/her own claim for benefits, causing confusion, possible duplicate payment, or payment of benefits to the enrollee rather than the provider (including physicians and suppliers).

EXAMPLE: The physician accepted assignment of a bill of $300 for covered services, and collected $60 from the enrollee after the Form CMS-1500 had been filed with the carrier, but before receiving notice of the Medicare allowed amount. The carrier determined that the Medicare allowed amount was $250, and since the Form CMS-1500 did not show any payment made by the enrollee, paid the physician $200 (80 percent of the $250 Medicare allowed amount). The result is that the physician has overcollected from the enrollee by $10.

When this overcollection came to light through a complaint from the enrollee, the carrier notified the physician that the $10 must be refunded to the enrollee. Unlike the excess payment made because the physician fails to show the amount collected on the claims form (see the example in B above), this $10 does not constitute a program overpayment; the carrier should not apply recovery procedures applicable to overpayments, and should not pay the $10 to the patient unless the physician first "refunds" it to the carrier (in lieu of refunding it directly to the patient).

If the physician, **after submitting his/her claim**, collects an additional amount on his/her bill, and the carrier learns of such collection before making SMI payment, the carrier should adjust its payments to the physician and enrollee accordingly. However, even if the physician collected the entire bill, requiring that the full SMI benefit be paid to the enrollee, the Medicare allowed amount limitations of the assignment still apply.

D. Durable Medical Equipment Supplier Bills for Coinsurance at the Time Claim Submitted

Notwithstanding the guideline in C above, a supplier of durable medical equipment may bill the beneficiary for 20 percent of the Medicare allowed amount at the same time it submits an assigned claim to the carrier for the items and services furnished*, with the exception of insulin that is administered through a covered item of DME. For such insulin see Pub. 100-04 Chapter 20, – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), Section 140.1.1 for further instruction*.

For all other items, the supplier must undertake:

1. To bill the beneficiary at the time it submits the claim only for 20 percent of the Medicare allowed amount; and

2. To inform the beneficiary prominently on its invoice that:

a. It has submitted a claim to the carrier for the items and services and he/she should not him/her self submit such a claim; and

b. The bill is for 20 percent of the Medicare allowable charge and is not covered by Medicare; and

3. To establish and maintain adequate procedures for refund of any over collections from the beneficiary that might result from the carrier approving a different Medicare allowed amount than that submitted.