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Office of the Attorney Advisor

JAN 16 2013

Mr. Felim Buckley
Novartis Pharmaceutical Corporation
One Health Plaza
East Hanover, NJ 07936-1080

Re: Novartis Pharmaceutical Corporation, Appeals CGDP 0000602012 and CGDP0000612012

Dear Mr. Buckley:

Enclosed is a copy of the Administrator's decision in the above case upholding the decision of the Independent Review Entity. This constitutes the final administrative decision of the Secretary of Health and Human Services.

Sincerely yours,

Jacqueline R. Vaughn
Attorney Advisor

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

Decision of the Administrator

IN THE MATTER OF:	*	Appeals CGDP0000602012 and CGDP0000612012
Novartis Pharmaceutical Corporation	*	
Pl008 Quarter 2 Appeals	*	
	*	Date: April 12 2012

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This case is before the Administrator, Centers for Medi-ea.re & Medicaid Services (CMS), for review of the decisions entered by Provider Resources, Inc. (PRI), the Medicare Coverage Gap Discount Program (Discount Program) Independent Review Entity (IRE). The review is pursuant to Section 1860D-14A(c)(l)(A)(vii) of the Affordable Care Act of 2010 and section V(g) of the Medicare Coverage Gap Discount Program Agreement (the Agreement).[1] The Novartis Pharmaceutical Corporation (Novartis) timely requested review of the IRE's decisions. Comments were timely-received from the Center for Medicare (CM). Accordingly, these cases are now before the Administrator for final agency review.

ISSUES AND INDEPENDENT REVIEW ENTITY DECISIONS

In Appeal CGDP0000602012, (hereinafter Appeal 1), the issue involves the IRE's decisions concerning whether Novartis was properly invoiced for the quantities

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[1] Section 1860D-14A(c)(l)(A)(vi.i) of the Act requires CMS to provide a reasonable mechanism to resolve manufacturer disputes involving the discounts provided under the Discount Program and section V of the Agreement specifies the rights and obligations of both CMS and manufacturers for resolving such disputes. A copy of the agreement can be found on the CMS website at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/CGDPMfrAgnntOriginal.pdf. See, also 75 Fed Reg. 29555 (May 26, 2010), "Medicare Program; Medicare Coverage Gap Discount Program Model Manufacturer Agreement and announcement of the Jan. 11, 2010 Public Meeting (CMS explained that "the model manufacturing agreement will be finalized and posted on the CMS website after we have considered the public comments and consult with manufacturers as required by Section 1860D-14(A)(a) of the Act." *Id.* at 29556.)

dispensed. In Appeal CGDP0000612012, (hereinafter Appeal 2) the issue concerns whether the drugs dispensed were applicable drugs within the parameters of the Medicare Coverage Gap Discount Program.

In Appeal 1, the IRE denied the appeal finding that the quantity dispensed was not aberrant, and the invoiced amounts were appropriate within the parameters of the Discount Program. The IRE reviewed the appealed National Drug Codes (NDCs) to review if the days' supply dispensed exceeded the CMS-specified threshold of three times the FDA approved maximum dose included in the appeals guidance. As a result of the IRE's review of the dispute file, the statements from the Part D sponsor, and its own analysis of the FDA maximum within the context of quantities dispensed, the IRE determined that Novartis was properly invoiced, The IRE stated that the applicable drugs were appropriately billed for the coverage gap discount dollars associated with the NDCs and the corresponding Detail Reference Numbers (DRNs), and denied Novartis' appeal based on Excessive Quantity.[2]

In Appeal 2, the IRE denied the appeal and found the drugs at issue were applicable drugs within the parameters of the Discount Program, The IRE noted that Novartis failed to show that the service providers dispensing the drugs were non-pharmacy providers. Therefore, the IRE determined that the drugs were covered under Part D because they were not dispensed by a physician provider incident to a physician's service.

COMMENTS

Novartis requested review of the IRE,s decisions based on the exceeding the maximum recommended dosage of applicable drugs, and Part B infusion or injectable drugs, in the respective appeals.

CM submitted comments stating, with respect to Appeal 1, that Novartis argued that the discounts must have been in error because the drugs dispensed exceeded the maximum FDA labeled dose. However, CM contended that Novartis failed to demonstrate that such doses, and quantities associated with such doses, were errors either because they were three times higher than the FDA maximum labeled dosing, represented a severe threat to the health of beneficiaries, were inconsistent with the packaging, or otherwise represented an unlikely dose in the Medicare population, Moreover, the Part D sponsor confirmed to the IRE that the drugs were

[2] DRNs are unique identifiers used by CMS for the Discount program when invoicing manufacturers to represent a pharmacy transaction and all subsequent actions including invoicing, payment, and appeals.

dispensed as specified by the beneficiaries' physicians and the IRE determined that all quantities dispensed were under the threshold specified in the CMS guidance. Thus, CM argued that the IRE properly concluded that the drugs were appropriately invoiced.

In Appeal 2, Novartis alleged that the drugs Zometa® and Reclast® should be covered under Medicare Part B, rather than Part D, because the drugs are generally not self-administered. CM argued that Medicare Part B pays for "not usually self-administered drugs" only when provided incident to a physician service. In order to be incident to a physician service, the physician must actually provide the drug from his or her own stock, and bill for the drug. CM noted that in this case, the IRE confirmed that all appealed DRNs were dispensed through pharmacies. Thus, CM argued that all the claims for Zometa® and Reclast® would not qualify for Medicare Part B coverage as incident to a physician service and could only be covered under Medicare Part D with applicable discounts for coverage gap claims.

In summary, CM argued that Novartis failed to demonstrate at any level of the dispute and appeal processes that the invoiced discount amounts were incorrect. Based on the information provided in the IRE decisions, CM requested that the Administrator uphold the IRE's decision that Novartis was appropriately billed for quarter two coverage gap discount payments.

DISCUSSION

The entire record furnished by the Independent Review Entity has been examined, including any written documents submitted. AU comments timely received are included in the record and have been considered,

Section l01 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended the Social Security Act (the Act) to, among other things, create a Medicare drug benefit program (Medicare Part D). The Patient Protection and Affordable Care Act and the Health Care Education and Reconciliation Act, collectively known as the Affordable Care Act (ACA) established the Discount program by adding §1860D-43 and §1860D-14A to the Act Under the program, the ACA made manufacturer discounts available to applicable Medicare beneficiaries receiving applicable drugs[3] while in the coverage gap The Coverage Gap, according to Chapter 5 of the Prescription Drug Benefit

[3] An applicable drug, as defined in §l860D-14A(g)(2) of the Act, is a covered Part drug that is either approved under a new drug application (NDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under §351 of the Public Health Service Act (BLA).

Manual, is defined as the gap phase in prescription drug coverage occurring between the initial coverage limit and the out-of-pocket threshold.

Generally, the discount on each applicable drug is 50 percent of an amount equal to the negotiated price. However, applicable drugs may be covered under Part D only if the manufacturer has a signed Medicare Coverage Gap Discount Program Agreement (Agreement) with CMS to provide the discount on coverage gap claims for all of its applicable drugs.[4] Beneficiaries then receive the manufacturer discount on applicable drugs at the point-of-sale, and the Part D sponsors subsequently submit prescription drug event (PDE) data to CMS.[5] Each Part D sponsor calculates the applicable discount for an applicable coverage gap claim and advances the discount to the beneficiary on behalf of the manufacturer.[6]

Through the use of a third-party administrator (TPA), CMS invoices manufacturers on a quarterly basis for those discounts provided by Part D sponsors. The invoices provide claim-level Manufacturer Data Reports containing Medicare Part D Discount Information along with each invoice that ails the · manufacturers liability for each coverage gap discount advanced to beneficiaries by Part D sponsors. The Agreement requires manufacturers to pay the Part D sponsor within 38 days of receipt of the quarterly invoice.

Section 1860D-14A(c)(l)(A)(vii) of the Affordable Care Act, established a mechanism to resolve manufacturer disputes involving the discounts provided under the Discount Program. Section V of the Discount Program Agreement specifies the rights and obligations of both CMS and the manufacturers for resolving such disputes. Manufacturers have the opportunity to file a dispute with the third party administrator about any of the invoiced amounts based on the 1\1.fodicare Part D Discount Information received on the Manufacturer Data report after payment is made. Within 60 days of receipt of the information that is the subject of the dispute, manufacturers must electronically submit all disputes to the TPA. To the extent a manufacturer receives an unfavorable dispute determination from the third party administrator; it has the right to appeal to the Independent

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[4] See, CMS guidance published on May 21, 2010.

[5] 42 CFR §423.4 defines Part D plan sponsor or Part D sponsor as a plan (PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage and/or a cost plan) offering qualified prescription drug coverage.

[6] Each Part D sponsor calculates the applicable 50 percent discount off of its negotiated price with the pharmacy and reports the discount payment amount to CMS through its normal Part D prescription drug event submission process.

Review Entity.[7] Manufacturers must demonstrate why the disputed discount payment likely is in error in order for the IRE to further review and validate a disputed discount payment.[8]

CMS issued guidance on May 31, 2011, that outlines the standards that manufacturer's appeals "must satisfy in order for the IRE to further review and validate a disputed discount program. The guidance identifies four bases upon which a manufacturer may challenge a discount payment: National Drug Code (NDC) Not on Market, Aberrant Quantity, Not Part D Covered Drug – Part B Ineligible for Discount, and High price of the Drug/Excessive Gap Discount.[9] Manufacturers bear the burden of proof in meeting these standards.

The May 2011 appeals guidance noted that there were several primary dispute reasons that may reasonably be appealed and clarified the expectations that manufacturers were to demonstrate on these appeals to justify further review and validation by the IRE. Relevant to Appeal 1, it stated in pertinent part:

> Aberrant Quantity: A quantity is considered aberrant if it represents a clearly excessive quantity for a given days' supply or is inconsistent with packaging of the product. Legitimate variations in patient characteristics and the therapeutic characteristics of drugs often warrant appropriate dosing in excess of FDA approved labeling. Therefore, appeals should be based on quantities that likely represent errors and not medically appropriate variation in dosing.
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> Generally; the IRE will further review and validate appeals based on the manufacturer's representation that the quantities represent greater than three times the maximum FDA labeled daily dose. To justify further review and validation by the IRE, manufacturers that appeals quantities that represent less than three times the maximum FDA labeled dose, or for any quantity.-related appeal if there is no maximum FDA labeled daily dose, will need to demonstrate that the dose represents a severe threat to the health of beneficiaries, is

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[7] Manufacturers may only appeal disputes that were initially submitted to the TPA and (1) have received a timely unfavorable determination from the TPA or, (2) were not resolved by the TPA within 60 days of submission. See, Section V(g) of the Medicare Coverage Gap Discount Program Agreement.

[8] See, Section V(g) of the Medicare Coverage Gap Discount Program Agreement.

[9] See,, Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 201L

> inconsistent with the packaging of the product, or otherwise represents an unlikely dose in the Medicare population.[10]

Relevant to Appeal 2, the May 2011 guidance states:

> Not Part D Covered Drug – Part B Drug Ineligible for Discount: Many prescription drug products that are covered under Medicare Part B may also be covered under Medicare Part D depending upon the patient and/or provider setting. For example, an injectible drug product that is covered under Medicare Part B when provided in a physician office from the physician's stock might be covered under Medicare Part D when dispensed by a pharmacy. Conversely, other drug products, such as oral anticancer drugs or IVIG, may be covered under Medicare Part B or Part D when dispensed by a pharmacy depending upon the indication and/or patient setting.
>
> Manufacturers that appeal a discount payment on the basis that the drug product is covered under Medicare Part B must specify which Medicare Part B coverage category is the basis for their appeal to justify further review and validation by the IRE, If the appeal is based upon an. injectible drug product being covered under Medicare Part B when provided incident to a physician's service, the Service Provider indicated on the detailed Manufacturer Data Report cannot be a pharmacy because pharmacies do not provide drugs in this particular Medicare Part B benefit category. If the appeal is based upon a Medicare Part B benefit category that may be dispensed from a pharmacy, the manufacturer must demonstrate that the claim likely should have been covered under Medicare Part B. The IRE may use Part D sponsors' previous B versus D coverage determinations as the basis for determining these appeals.[11]

In March 2012, CMS provided additional industry guidance for the Discount Program disputes. CMS specified the standards that manufacturers must satisfy in order for the TPA to review and validate a disputed discount payment. The document gives general guidance for disputes and also gives dispute submission requirements by dispute reason for Duplicate Invoice Item, Closed Pharmacy, Not a Part D Drug, Excessive Quantity, Days Supply, High Price of the Drug, Last Lot

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[10] See, Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011

[11] See, Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011

Expiration Date, Early Fill, Marketing Category Not a Biologic License Application (BLA) or New Drug Application (NDA) and Other.[12]

Moreover, the dispute guidance states that "CMS will deny disputes if the discount payment is accurately calculated, even if the dispensing event may not have been clinically appropriate." In other words, the dispute process is not intended to be a retrospective utilization management review where the clinical decision making of the prescriber, provider, or Part D plan is called into question. Manufacturers are expected to pay discounts on all applicable drugs which were dispensed to applicable beneficiaries even if the manufacturer believes that the dosages dispensed were inappropriate.[13]

The 2012 Dispute guidance reiterates the importance of looking at the setting in which the drug was dispensed for drugs disputed for Medicare Part B versus Part D. It states that "manufacturers wishing to dispute for this reason should first confirm that the Service Provider ID field on the invoiced NDC in question does not represent a pharmacy. Absent any clinical review, if a drug that can be covered under Part B or Part D is dispensed through a pharmacy, we can only assume that the indication or patient setting supports being billed correctly under Part D.[14]

In the instant cases, Novartis contracted with CMS to participate in the Discount program beginning in January 2011. Under the terms of the Discount Program Agreement; Novartis submitted the following labeler codes for applicable drugs to be covered under Part D: 00028, 00065, 00067, 00078, 00083, 00185, 00781, 00998, 42515, 42826, 43068, 46028, 58768, 61314, 63851, 66521, 66685, and 66758.[15]

On September 1, 2011 Novartis received its second quarter 2011 invoice covering discounts provided to Medicare Part D beneficiaries in the coverage gap from April 1, 2011 through June 20, 201 L The total invoice was for $7,399,43654 and was due to be paid by October 9, 201 L[16] Novartis paid the invoice through electronic funds transfer on September 27, 201 L On October 20, 2011, Novartis submitted to

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[12] See, e.g. Medicare Coverage Gap Discount Program – Dispute Resolution, dated March 5, 2012.

[13] See, Medicare Coverage Gap Discount Program – Dispute Resolution, dated March 5, 2012.

[14] See, Medicare Coverage Gap Discount Program – Dispute Resolution, dated March 5, 2012.

[15] See, CM's Comments, Exhibit 6, Health Plan Management System Screen Shot of Novartis Labeler Codes.

[16] See, Coverage Gap Discount Program Manufacturer Invoice for Quarter 2, 2011, Novartis Pharmaceuticals Corporation, P1008.

Palmetto, CMS' TPA, disputes for 97 detail reference numbers (DRNs) using dispute reason codes:

> D04, "Excessive Quantity" was used to dispute 32 DRNs. Novartis included "Max Dosage" amounts for each drug in the notes section of the dispute file.
>
> D03, "Not a Part D drug" was used to dispute 65 DRNs. The dispute notes stated "product Service ID is not eligible for Coverage Gap Discount Part B drug, Infusion Drug. Not usually self administered.[17]

On December 30, 2011 the TPA sent Novartis notification that all of the disputes had been denied. On January 18, 2012, Novartis then filed 2 appeals with CMS' contracted IRE.[18] In Appeal 1, Novartis challenged discounts for 15 NDC's which include 8 drugs: Comtan®, Diovan®, Enablex®, Exelon Patch®, Myfortic®, Stalevo®, Tektuma®, and Vivelle®.[19] The IRE requesteJhat all involved Part D sponsors affirm that the drug quantities included on the invoices were indeed dispensed. The IRE also reviewed the appealed NDCs to see if the days' supply dispensed exceeded the CMS-specified guidance. In Appeal 2, the Novartis contended that their drugs Zometa® and Reclast®, were not applicable drugs for purposes of the Discount program because they are covered under Medicare Part B, Novartis claimed that the drug is administered by intravenous infusion, and therefore must be administered by qualified healthcare professionals. As a result, Novartis argued that the dmgs were covered under .Medicare Part B, and not Part D, The IRE concluded that the drugs were dispensed by pharmacies rather than physicians, and therefore, covered under Part D.

The Administrator finds that the regulations at §l860D-43 and §1860D-14A of the Act delineate the parameters of the Discount Program. The May 2011 appeals guidance provided standards that manufacturer appeals must meet in order for the IRE to review and validate a disputed discount program claim. In addition, relevant to this appeal; the Administrator notes that the l\Aarch 5, 2012 Dispute Resolution Guidance further provides an explanation of the dispute reason codes, and specifically states in pertinent part, consistent with the earlier guidance, that:

> D04, Excessive Quantity:
> Manufacturers who file a dispute on the basis that the quantity is excessive should demonstrate that the quantity is inconsistent with

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[11] See, CM's Comments, Exhibit 8, Novartis Pharmaceutical Corporation Quarter 2 TPA Dispute Resolution file.

[18] See, CM's Comments, Exhibit 9, Novartis Quarter 2 IRE Appeal Submission.

[19] See, Independent Review Entity's Decision, Appeal CGDP0000602012, pgs. 3-5.

> the packaging of the product and that the quantity is considered excessive given the days' supply. Legitimate variations in patient characteristics often warrant approximate dosing in excess of the Food and Drug Administration (FDA) approved labeling. When there is a maximum FDA labeled daily dose, CMS will generally not uphold disputes "for quantities that represent doses less than three times the maximum. Disputes should be based on quantities that likely represent errors that are not medically appropriate under any circumstances and may represent a threat to the health of a Medicare beneficiary.
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> D03, Not Part D Covered Drug:
> ...The purpose of this code is for manufacturers to indicate that an NDC should not be covered under the Part D program under any circumstances. Manufacturers should not use the dispute reason code of 'Not Part D Covered Drug" to file a dispute Qn the basis that the drug is potentially a non-applicable CGDP drug, but otherwise would be covered under Medicare Part D. ... Additionally, we note that drugs disputed for Medicare Part B vs. Part D coverage are largely dependent on indication and/or patient setting. Manufacturers wishing to dispute for this reason should first confirm the Service Provider ID field on. the invoiced PDE in question does not represent a pharmacy., Absent any clinical review, if a drug that can be covered under Part B or Part D is dispensed through a pharmacy, we can only assume that the indication or patient setting supports being billed correctly under Part D. Therefore, disputed PDEs meeting these criteria will be denied.

The CMS Discount Program appeals guidance specifically stated thatj "'a discount payment is in error only if it is not accurately calculated or if it is not calculated based upon accurate data that represents the dispensing event that actually occurred."'[20] It further explains that "it is not an error if the discount payment is accurately calculated based upon accurate data for dispensing events that actually occurred even if the amount calculated appears to indicate that the dispensing event may not have been clinically appropriate."[21] Thus; the dispute and appeals process is not intended. to be a retrospective utilization management review where the clinical decision making of the prescriber, provider, or Part D plan is called into question. The guidance noted that legitimate variation in patient characteristics and therapeutic characteristics of drugs often warrant appropriate dosing in excess of

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[20] See, Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, pg. 2.
[21] *Id*. at pg. 3.

FDA approved labeling and consequently established a threshold of three times the maximum FDA labeled daily dose as warranting further review unless the manufacturer demonstrates that lower doses represent "a severe threat to the health of beneficiaries, is inconsistent with packaging of the product, or otherwise represents an unlikely dose in the Medicare population."[22]

In Appeal 1, Novartis argued that the discounts were in error because the drugs dispensed exceeded the maximum dose listed on the FDA-approved label for all appealed drugs except Tekturna® which Novartis argued the quantities represented greater than three times the maximum FDA labeled daily dose. The record shows that Novartis failed to demonstrate that such doses, and the quantities associated with such doses were likely errors either because they were three times higher than the FDA maximum labeled dosing, represented a severe threat to the health of beneficiaries, or were inconsistent with the packaging or otherwise represent an unlikely dose in the Medicare population. The Part D sponsors have provided coverage for appealed drugs for these beneficiaries because they have determined that the quantities dispensed represent medically appropriate variations in dosing. In the instant case, the Part D sponsor confirmed to the IRE that the dmgs were dispensed as specified by the beneficiaries' physicians[23] and the IRE determined that all quantities dispensed were under the threshold specified in the CMS guidance.[24] For example, Novartis appealed the DRN for Comtan® 200mg. The maximum dosage for 90 days is 720 units. The prescription drug event was validated by the plan sponsor; and it explained that "the CMS approved compendia of Micromedex lists the FDA approved use of this drug as Parkingson's Disease, The provider felt the patient was a refractory case and therefore the disease has been difficult to treat. The provider started with a high dose to combat the difficult nature of treating patients who are not responding to other therapies."[25] The dosing information for this drug is 200 mg up to eight times a day,[26] The calculation for the maximum. FDA-approved dose based on quantity dispensed was 720 tablets for a 90 day supply, and the quantity equal to 3 times the FDA-approved Maximum Dose is 2160 tablets for 90 days. The actual quantity dispensed was 810 tablets for 90 days, which although is higher than the maximum FD.A.-approved amount, is still lower than 3 times the maximum dose amount.[27] The Administrator notes that "legitimate variations in patient characteristics and the therapeutic characteristics of drugs often warrant appropriate dosing in excess of FDA approved labeling."[28]

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[22] *Id.*

[23] See. Independent Review Entity Decision, Appeal CGDP0000602012, Table 2: Part Sponsor "Verification Response for Dispensing Information, pgs. 6-10.

[24] See, Independent Review Entity Decision, Appeal CGDP0000602012, dated April 12, 2012, pg. 12.

[25] See, Independent Review Entity Decision, Appeal CGDP0000602012, Table 2: Part D Sponsor Verification Response for Dispensing Information, pg. 6.

[26] See, Independent Review Entity Decision, Appeal CGDP0000602012, Table 3: FDA Dosing Information, pg. 10.

Thus, the actual quantity filled and days supply for this drug, along with the others appealed in this case, were not aberrant and appropriately dispensed within the parameters of the program in Appeal 1.

In Appeal 2, Novartis asserted that their drugs Zometa® and Reclast® should be covered under Medicare Part B, rather than Part D, as they are generally not self-administered drugs, Manufacturers that have signed Agreements are required to provide discounts for 'applicable drugs;' to 'applicable beneficiaries." An applicable drug, as defined in §1860D-14A(g)(2) of the Act, is a covered Part D drug that is either approved under a new drug application (NDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under §351 of the Public Health Service Act (BLA). The CMS Medicare Benefit Policy Manual, at Chapter 15, §502 and §503, explains that IV!edicare Part B covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients. The charge for the drug, if any, must be included in the physician s billing. The cost of the drug charged must represent an expense to the physician in order to be considered "incident to" the physician's service.

The Medicare Prescription Drug Benefit Manual, in Chapter 6, Appendix C, also states that drugs are covered under Medicare Part B if furnished "incident to" a physician's service. More specifically, injectable or intravenous drugs, administered predominantly by a physician or under a physician's direct supervision as "incident to" a physician's professional service qualify as covered under Medicare Part B. In order to meet all the general requirements for coverage under the "incident to" provision, an FDA-approved drug or biological unit must:

- Be of a form that is not usually self-administered;
- Be furnished by a physician; and
- Be administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision.

The Chapter 6 guidance also states, "if a network pharmacy supplies the drug directly to the beneficiary, the drug must be accounted for under its Part D benefits."'

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[27] *Id.*

[28] See, Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, pg.3.

The Administrator notes that Medicare Part D pays for drugs that otherwise meet the definition of a Part D drug, including "not usually self-administered drugs," if not covered under Medicare Part A or Part B, as prescribed and dispensed or administered with respect to that individual. Medicare Part B pays for "not usually self-administered drugs," such as Zometa® and Reclast®, only when provided "incident to a physician service." As explained in the manuals, in order to be "incident to a physician service," the physician must actually provide the drug from his or her own stock, or rather, the physician must bill for the drug. Consequently, if a pharmacy dispenses and bills for a "not usually self-administered drug," it does not meet the Medicare Part B "incident to physician services" requirements and therefore can only be covered under Part D.

The record shows that all the appealed DRNs were dispensed through pharmacies.[29] The table listing the Service Provider Identifier Qualifier, the Service Provider Identifiers, and the Classification clearly show that the drugs were dispensed by a pharmacy, mail order pharmacy, specialty pharmacy, clinic pharmacy, home infusion therapy pharmacy) or community/retail pharmacy.[30] Consequently, all of these claims for Zometa® a:nd Reclast® would not qualify for Medicare Part B coverage as ·incident to a physician service" and could only be covered under Medicare Part D with applicable discounts for coverage gap claims. As a result, the claims in Appeal 2 were appropriately billed under the coverage gap discount program.

In these cases, the Administrator finds that Novartis failed to demonstrate at any level of the dispute and appeal process that the invoiced discount amounts were incorrect Therefore, the Administrator finds that the IRE properly determined that Novartis·was appropriately billed for Quarter two coverage gap discounts, with respect to Appeal l and Appeal 2.

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[29] See, Independent Review Entity Decision, Appeal CGDP0000612012, Attachment A, pgs. 6-9.

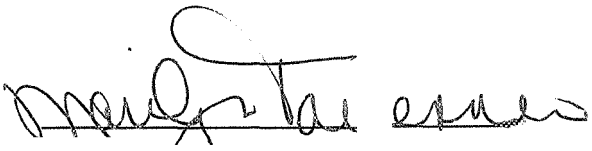
[30] *Id.*

DECISION

In light of the foregoing and based on the record, the Administrator hereby upholds the decision of the Independent Review Entity in Appeal 1 - CGDP0000602012, and Appeal 2 - CGDP0000612012.

THIS CONSTITUTES THE FINAL ADMINISTRATIVE DECISION OF THE SECRETARY OF HEALTH AND HUMAN SERVICES

Date: 1/8/13



Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services