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Office of the Attorney Advisor

FEB 6 2015

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

Re: Novartis Pharmaceutical Corporation, Appeal CGDP0001592013

Dear Mr. Buckley:

Enclosed is a copy of the Administrator's decision in the above case upholding Decisions A and B of the Independent Review Entity as modified. 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 CGDP0001592013**
Novartis Pharmaceutical Corporation	*	
P1008 - Quarter 1 - 2013 Appeal	*	**Date: December 20, 2013**

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This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the decision 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 decision.[2] Comments were timely received from the Center for Medicare (CM). Accordingly, this case is now before the Administrator for final agency review.

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[1] Section 1860D-14A(c)(l)(A)(vii) 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). Provisions of the Manufacturer Agreement were codified in the final rule at 77 Fed Reg. 22079 (April 12, 2012) effective June 1, 2012.

[2] *See* n. 1, The administrative review process was codified in the regulation at 42 CFR §423.2330(c), 77 Fed Reg. 22072 (April 12, 2012).

ISSUE AND INDEPENDENT REVIEW ENTITY DECISION

In this appeal, the issue involves the IRE's decisions concerning whether Novartis demonstrated that the first quarter 2013 Discount Program invoice was in error. Novartis advanced the arguments of High Price of Drug and Excessive Quantity, and reasoned that the specified current Reported Gap Discount amount exceeds the maximum possible discount. The IRE reviewed the appealed 18 National Drug Codes (NDCs) for 1,041 Detail Reference Numbers (DRNs).[3] In Decision A, the IRE found that 873 of the appealed DRNs, were invoiced at an amount greater than the maximum possible discount of a single claim of $2,435.89 (50% of $4,871.78). Thus, the IRE affirmed Novartis's appeal for these DRNs at issue and copied CMS on the appeal decision response to ensure the respective PDEs were corrected.[4] In Decision B, the IRE found 168 of the appealed DRNs were invoiced at an amount less than the maximum possible discount of a single claim, and were, thus, appropriately billed for the coverage gap discount dollars. The IRE therefore denied Novartis' appeal based on High Price of Drug and Excessive Quantity for the appealed drugs in Decision B.[5]

COMMENTS

Novartis requested review of the IRE's decision based on the High Price of Drug and Excessive Quantity, in the instant case.

CM submitted comments stating that Novartis argued that the price of the drugs which provided the basis for the discount amount was excessive, and therefore it is not responsible for the full amount invoiced. CM noted that Novartis appealed the disputed amounts to the IRE stating that the Prescription Drug Event (PDE) exceeded the Manufacturer's maximum possible discount of $2,375 or 50% of the Coverage Gap for the 2013 benefit year."[6] However, CM stated that in accordance with the CMS March 4, 2014 guidance, the 2013 maximum manufacturer discount was $2,435.90.[7] CM further stated that Novartis failed to submit any additional data to support its appeal and show that the amounts appealed exceeded amounts specified in CMS guidance. Despite Novartis's failure to meet the burden of proof outlined in CMS guidance, the IRE confirmed the accuracy of each discount

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[3] DRNs are unique identifiers used by CMS for the Part D Coverage Gap Discount Program when invoicing manufacturers to represent a pharmacy transaction and all subsequent actions including invoicing, payment, and appeals.

[4] *See,* IRE Decision, Appeal CGDP0001592013, Decision A, at pgs. 5-30.

[5] *See,* IRE Decision, Appeal CGDP0001592013, Decision B, at pgs. 31-35.

[6] *See,* CM Comments, Appeal CGDP0001592013, dated June 4, 2014.

[7] The calculation shows that 50 percent of $4871.78 is $2435.895, hence CMS rounds up to $2435.90.

calculation. CM requested that the Administrator uphold the IRE's decision that Novartis was appropriately billed for first quarter 2013 coverage gap discount payments for the denied DRNs.[8]

DISCUSSION

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

Section 101 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA)[9] amended the Social Security 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[10] and §1860D-14A to the Act. Under the program, the ACA made manufacturer discounts available to applicable Medicare beneficiaries receiving applicable drugs[11] while in the coverage gap. The Coverage Gap, according to Chapter 5 of the Prescription Drug Benefit 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[12] has a signed Medicare Coverage Gap Discount Program

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[8] *Id.*

[9] Pub. Law.108-173.

[10] Section 1860D-43 of the Social Security Act, "Conditions for Coverage of Drugs under this Part", provides: " (a) IN GENERAL-In order for coverage to be available under this part for covered part D drugs (as defined in section 1860D-2(e)) of a manufacturer, the manufacturer must- (1) participate in the Medicare coverage gap discount program under section 1860D-14A; (2) have entered into and have in effect an agreement described in subsection (b) of such section with the Secretary; and (3) have entered into and have in effect, under terms and conditions specified by the Secretary, a contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of such section."

[11] 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).

[12] Section 1860D-43(d) of the Social Security Act states: "Definition of Manufacturer".-In this section, the term "manufacturer" has the meaning given

Agreement (Agreement) with CMS to provide the discount on coverage gap claims for all of its applicable drugs.[13] 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.[14] 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.[15]

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 details the manufacturer's 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 Medicare 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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such term in section 1860D-14A(g)(5)." Section 1860D-14A(g)(5) states that: 'The term "manufacturer" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law."

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

[14] 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.

[15] 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. [16] 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.

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 primary basis 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. [17] 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 this appeal, it stated in pertinent part:

> High Price of the Drug/Excessive Gap Discount: A maximum gap discount amount is 50% of the negotiated price (less supplemental gap benefits, dispensing fee, and vaccine administration fee) between the Part D sponsor and the pharmacy as documented in the September 24, 2010 guidance entitled "Prescription Drug Event Edit Guidance Effective January 1, 2011." CMS performs an outlier analysis on PDE records to validate gap discount amounts prior to invoicing. Considering that manufacturers do not have access to the actual negotiated price of a drug between a Part D sponsor and a pharmacy, the manufacturers will need to provide other reliable information to demonstrate that the gap discount amount is excessive and likely in error to support further review and validation by the IRE.[18]

In March 5, 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

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

[17] *See,* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011.

[18] *See,* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011 at. 4.

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 Expiration Date, Early Fill, Marketing Category Not a Biologic License Application (BLA) or New Drug Application (NDA) and Other.[19]

> High Price of Drug (D06)
>
> Under this dispute reason code, we have observed several additional issues being disputed. Concerns over the maximum discount per PDE and cumulative maximum discount for a single beneficiary should be file under D99[[20]] at this time. ....
>
> Appropriate disputes field under reason code D06 reason code call into question the unit price of the disputed NDC. To evaluate these disputes, CMS analyzes the per unit price of the disputed PDEs relative to all other PDEs accepted for the same NDC. If the price falls within an acceptable range according to actual PDE data the dispute is denied.
>
> We have observed a number of D06 disputes based upon non-Part D pricing metrics. Under section 1860D-2(d) of the Act, Medicare Part D negotiated prices are not determined by formula and may differ by plan, as each sponsor enters into private negotiations to determine the price. We remind manufacturers that CMS is prohibited by section 1860D-1l(i) of the Social Security Act from interfering "with the negotiations between drug manufacturers and pharmacies and PDP sponsors" and CMS "may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." Since Part D negotiated prices are not determined by statutory formula (e.g., the average sales price (ASP) plus 6% used for Medicare Part B drugs or the average manufacturer price (AMP) used in the Medicaid drug rebate program) and are not specifically tied to common list prices such as average wholesale price (AWP) or wholesale acquisition cost (WAC), we do not consider these price

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

[20] *See*, Medicare Coverage Gap Discount Program – Dispute Resolution, dated March 5, 2012 at 7. *("Other (D99)* Manufacturers have used the D99 dispute code to capture a variety of different concerns. The top three issues under dispute are the following: ....2. *Maximum Gap Discount Disputes ....")*

> points when evaluating the per unit price of a drug. Disputes should not be submitted solely based upon a calculated deviation between the Part D negotiated price and prices from other government programs or list prices. **Disputes citing only these sources as the basis for the dispute will generally be denied unless the PDE in question also exceeds a threshold in the actual Part D data.** [Emphasis added][21]

The guidance further explained that disputes citing only these sources as the basis for the dispute will generally be denied unless the PDE in question also exceeds a threshold in the actual Part D data. It advised that manufacturers may want to consider using the "Prescription ·Drug Plan Formulary, Pharmacy Network, and Pricing Information Files" to guide their decisions with respect to pricing outliers. These public use files (PUF) contain average monthly costs for formulary Part D drugs, and outlier models could be developed using these data to determine prices that substantively deviate from the average.[22]

The Attached "Summary of Dispute Submission Guidance by Reason Code" set forth the expected supporting Documentation stating for dispute reason code 06 for "High Price of the Drug" as follows:

> REQUIRED:
> The ADDITIONAL INFORMATION field should contain supporting evidence that demonstrates that:
> • The per unit price is excessive relative to the per unit price paid under the Part D program.
>
> Manufacturers should not cite AMP, ASP, AWP, WAC or other non-Part D pricing benchmarks as a basis for the claim of high per unit price of a disputed PDE. Medicare Part D negotiated prices are not determined by formula and may differ by plan, as each sponsor enters into private negotiations to determine the price.

Relevant to the instant case, CMS issued guidance on January 27, 2012, which explained the Coverage Gap. It specifically states:

> The Part D benefit parameters for defined standard coverage are established annually in accordance with statutory requirements. In 2011, the defined standard coverage includes a $310 deductible, a 25

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[21] *See,* Medicare Coverage Gap Discount Program – Dispute Resolution, dated March 5, 2012 at 4.
[22] *Id.*

> percent cost-sharing between the deductible and initial coverage limit (ICL) a $2840 ICL, and an out-of-pocket threshold of $4550. Under this benefit design, a beneficiary would have incurred $942.50 in out-of-pocket spending when they · reach the ICL. Therefore, the beneficiary would have $3607.50 remaining in out-of-pocket spending before reaching the annual out-of-pocket threshold.

Nonetheless, most Part D plans do not offer defined standard coverage, and Part D sponsors frequently provide benefits that are actuarially equivalent to the defined standard coverage or enhanced with lower deductibles and fixed co-pays rather than the 25% co-insurance before the Initial Coverage Limit, or ICL. Consequently, beneficiaries will -have incurred different levels of out of-pocket spending when they reach the ICL depending upon their specific Part D plan benefits parameters.

The January 27, 2012 guidance defined the maximum possible discount on a single claim, and stated:

> An applicable discount is equal to fifty percent of the portion of the negotiated price (as defined in 42 CFR 423.100 but excluding any dispensing fee) of an applicable drug of a manufacturer that falls within the coverage gap.
>
> While total part D drug costs gets a beneficiary into the coverage gap, only out-of-pocket costs incurred by the beneficiary, or counted as if incurred by the beneficiary, move the beneficiary towards the annual out-of-pocket threshold. These costs are referred to as true out-of-pocket (TrOOP) costs.[23]

In the instant appeal, Novartis received its first quarter 2013 Invoice Report 201202, covering discounts provided to Medicare Part D beneficiaries in the coverage gap from January 1, 2013 through March 26, 2013. On June 20, 2013, Novartis submitted to the CMS' TPA, disputes alleging that the "PDE exceeds the maximum benefit discount of $2,375.00 for the 2013 benefit year" for each DRN. The TPA denied Novartis's disputes on August 29, 2013, reaffirming the drugs at issue were calculated within the maximum allowable amount. Novartis submitted an IRE appeal on September 23, 2013.[24] Novartis appealed 1,041 DRNs having 18 National Drug Codes (NDC's) which included the following drugs: Afinitor® lOmg, Afinitor® 2.5mg, Afinitor® 5mg, Afinitor® 7.5mg, Exjade® 125mg,

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[23] *See,* Medicare Coverage Gap Discount Program ·- Maximum Applicable Discounts, dated January 27, 2012.

[24] *See,* IRE Decision, Appeal CGDP0001592013, at 3.

Exjade® 250mg, Exjade® 500mg, Extavia® Kit, Gilenya® 0.5mg, Gleevec® 1OOmg, Gleevec® 400mg, Sandostatin® Lar Depot 20m¥: Kit, Sandostatin® Lar Depot 30mg Kit, Tasigna® 150 mg, and Tasigna® 200mg. [5]

In its request to the TPA, Novartis identified "Dl 3" under "Dispute Reason Code." The file format layouts provided by CMS through the TPA to manufacturers on March 5, 2012, shows that dispute code "Dl 3" is an invalid code. Novartis argued that the "PDE exceeds the Manufacturer's maximum possible discount of $2,375.00 or 50% of the Coverage Gap for the 2013 benefit year." On appeal to the IRE, Novartis advanced the same argument that was submitted for review to the TPA. Thus, at issue in this appeal is the Maximum Gap Discount amount from a PDE submitted by an Employer Group Waiver Plan (EGWP).[26] According to the data submitted, the DRNs at issue had a 2013 date of service and were invoiced at an amount greater than the maximum possible discount of a single claim of $2,435.90 (50% of $4,871.78). Moreover, Novartis did not submit any additional data to the IRE or the Administrator in support of its appeal.

At issue in this appeal is the maximum allowable discount. CMS guidance dated January 27, 2012 states:

> An applicable discount is equal to fifty percent of the portion of the negotiated price ... of an applicable drug of a manufacturer that falls within the coverage gap.[27] In 2011, the maximum possible discount on a single claim is $2275 (or 50% of $4550). The maximum coverage gap will increase to $4700 in 2012 and, therefore, the maximum possible discount on a single claim in 2012 will be $2350 (or 50% of $4700).[28]

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[25] *See,* IRE Decision, Appeal CGDP0001592013, Attachment A, which identifies the DRNs, NDCs, Drugs, Reported Gap Discount Current Amount, Gap Discount Amount This period, Amount Invoiced, and Amount Appealed, at pgs. 5-35.

[26] *See,* Medicare Managed Care manual, Chapter 9, Employer/Union Sponsored Group Health Plans for EGWPs discussion.

[21] "Coverage Gap" is defined as the gap phase in prescription drug coverage that occurs between initial coverage limit (as defined in §1860D-2(b)(3)) and the out-of-pocket threshold (as defined in §1860D-2(b)(4)(B)). *(See,* Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance, dated May 21, 2010.

[28] *See,* Medicare Coverage Gap Discount Program-Maximum Applicable Discounts, dated January 27, 2012 at 3.

However, beginning in 2013, Medicare Part D plans provided increased coverage for brand drugs at a level of 2.5% of the negotiated drug costs.[29] This 2.5% is not paid for by the beneficiary and therefore cannot be counted towards TrOOP. In 2013, the TrOOP is $4,750 and the Medicare plan covers 2.5% of the negotiated drug costs. Therefore; the discountable amount is extended to $4,871.79 ($740/.975). Thus, the maximum discount on a single PDE is $2,435.90 (50% of $4,871.79).

Consistent with this policy, CMS offered further clarification in its March 4, 2014 guidance, stating, in pertinent part:

> In 2013 and 2014, the beneficiary pays 47.5% of the negotiated price of applicable drugs, the Part D plan pays 2.5%, and the pharmaceutical manufacturer pays 50% of the coverage gap.
>
> While total Part D drug costs move a beneficiary into the coverage gap, only true out-of-pocket (TrOOP) costs move the beneficiary towards the annual out-of-pocket threshold.
>
> The revised maximum discount formula incorporates both the annual TrOOP amounts as well as the gradual increase in basic Part D coverage in the coverage gap.. For example, in 2013, TrOOP is $4750 and the Medicare plan covers 2.5% of the negotiated drug costs. Therefore the maximum manufacturer discount is $2435.90 [($4750/.975) x .50]. The formula starts with remaining TrOOP and is divided by the cost-sharing percentages of the beneficiary and the manufacturer to determine the negotiated price that coincides with remaining TrOOP. Once this amount is determined, then the cost-sharing portions for the manufacturer, beneficiary, and plan can be calculated.
>
> Due to the additional Medicare contribution to drug costs in the gap, the maximum discount for a single claim is to be calculated as follows:

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[29] *See* Attachment IV: Final Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and retiree Drug Subsidy in *Announcement of Calendar Year (CJ] 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,* April 2, 2012.

TrOOP dollar amount / (beneficiary + manufacturer gap payment percentages) x .50

The formula can be broken down into two steps:

1. Determine the negotiated price associated with a beneficiary's remaining TrOOP:
   TrOOP Dollar amount / (beneficiary + manufacturer gap payment percentages) = gap eligible portion of negotiated price

2. Determine the manufacturer's portion of the negotiated price:

   Gap Eligible Portion of Negotiated Price x .50 = Gap Discount[30]

For the 873 DRNs appealed in Decision A, at issue is the Maximum Gap Discount from a PDE submitted by an Employer Group Waiver Plan (EGWP). According to the data submitted, the DRNs at issue had a 2013 date of service and were invoiced at an amount greater than the maximum possible discount of a single claim of $2,435.90 (50% of $4,871.78).[31] The Administrator finds for the 873 DRNs at issue, that the IRE correctly affirmed Novartis's appeal, and the PDE should be corrected.

With respect to the remaining 168 DRNs in Decision B, the issue also concerns the Maximum Gap Discount amount from the PDE submitted by an EGWP. According to the data submitted, the DRNs at issue had a 2013 date of service and were invoiced at an amount less than the maximum possible discount of a single claim of $2,435.90 (50% of $4,871.78).[32] The record indicates that all of the 168 DRNS at issue in Decision B were below the maximum possible discount claim of $2,435.90.[33] Novartis did not provide additional explanation to support this assertion, nor did it provide any additional pricing information or other accompanying documentation. The Administrator finds that the manufacturer bears the burden of proof to demonstrate that the gap discount was excessive or

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[30] *See,* Medicare Coverage Gap Discount Program – Maximum Applicable Discounts Updates, dated March 4, 2014 at pgs 2-3.

[31] *See,* IRE Decision, Appeal CGDP0001592013, Attachment A, for the applicable DRNs, NDCs, Drugs, Reported Gap Discount Current Amount, Gap Discount Amount This Period, Amount Invoiced, and Amount Appealed.

[32] *See,* IRE Decision, Appeal CGDP0001592013, Attachment B, for the applicable DRNs, NDCs, Drugs, Reported Gap Discount Current Amount, Gap Discount Amount This Period, Amount Invoiced, and Amount Appealed.

[33] *Id.*

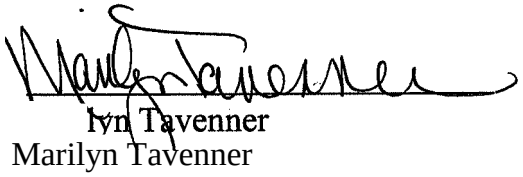
calculated incorrectly. In addition, the record does not support that the 168 PDEs in question exceeded a threshold in the Part D data. Accordingly, the Administrator finds that the drugs were appropriately billed for the coverage gap discount dollars associated with the NDCs and the corresponding 168 DRNs, in Decision B.

DECISION

In light of the foregoing and based on the record, the Administrator hereby upholds Decisions A and B of the Independent Review Entity in this Appeal, as modified herein.

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

Date: 1/29/15



Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services