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CENTERS FOR MEDICARE & MEDICAID SERVICES

Office of the Attorney Advisor

JUN - 4 2014

Ms. Mary Jo Farinella-Evans
DAVA Pharmaceuticals, Inc.
Parker Plaza
400 Kelby Street, 10th Floor
Fort Lee, NJ 07024

Re: DAYA Pharmaceuticals, Inc., Appeal CGDP0000792012

Dear Ms. Farinella-Evans:

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:	*	**Appeal CGDP0000792012**
	*	
DAVA Pharmaceuticals, Inc.	*	
P1103	*	
	*	
	*	**Date: June 4, 2012**
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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] DAVA Pharmaceuticals, Inc. (DAVA) 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.

ISSUE

The issue involves whether the IRE properly determined that DAVA failed to demonstrate that the third quarter, 2011 invoice for coverage gap discounts was incorrect in accordance with the Discount Program Agreement, CMs Guidance and applicable law.

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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/CGDPMfrAgrmtOriginal.pdf See also 75 Fed. Reg. 29555 (May 26, 2010) ("Medicare Program; Medicare Coverage Gap Discount Program Model Manufacturer Agreement and Announcement of the June 1, 2010 Public Meeting.") (CMS explained that, '"The model manufacturer agreement will be finalized and posted on the CMS Web site after we have considered the public comments and consulted with manufacturers as required. by section 1860D-14A of the Act.") *Id.* at 29556,

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

BACKGROUND AND IRE DECISION

DAVA was invoiced for the third quarter 2011 for an applicable drugs having National Drug Codes or "NDCs" with the Manufacturer's (DAVA's) labeler code(s). DAVA was invoiced on Invoice Report 201103 for furosemide 20 mg and furosemide 40 mg, which included their corresponding NDCs. DAVA filed a dispute with the Third Party Administrator (TPA) on November 2, 2011 for 97 Detail Reference Numbers (DRNs) having NDCs 67253-0540 10 and 67253-0540-11 (for furosemide 20mg) and 67253-0541-10 and 67253-0541-11 (for furosemide 40mg) with dates of service January 19, 2011 through September 15, 201 I. DAVA stated that these drugs should not have been invoiced, as they were approved under an "Abbreviated New Drug Application" (ANDA), rather than a "New Drug Application" (NDA). The TPA denied DAVA's dispute on March l, 2012, stating that the drugs at issue were invoiced properly.

DAVA submitted an appeal to Independent Review Entity (IRE) on March 8, 2012. The IRE received the dispute information submitted by DAVA to the TPA in the electronic Manufacturer Dispute Submission File for the appealed DRNs. Under "Dispute Reason Code", DAVA identified "D03", meaning, "Not Part D Covered Drug." In the field "Additional Information", for each DRN, DAVA asserted that the drug was approved under an ANDA, rather than an NDA, making it not a covered under the Part D Drug. On appeal to the IRE, DAVA additionally asserted "D09" in the "Explanation for IRE Review Reques" field" "D09" stands for "Marketing Category is not New Drug Application (NDA) or Biological Licensing Agreement BLA)." DAVA submitted a letter date-stamped August 7, 2006, from the Food and Drug Administration (FDA) regarding supplemental New Drug Applications and furosemide.

The IRE's review of furosemide 20 mg and 40 mg included consideration of the TPA's dispute review information, information provided by the manufacturer to the TPA for the dispute review, a review of the FDA New National Drug Code Directory[3] (New NDC Directory), the FDA Old National Drug Code Directory[4] (Old NDC Directory), and the FDA Electronic Orange Book (Orange Book).[5] While the New NDC Directory did not list the drugs at issue, the Old NDC Directory and Orange Book both listed the drugs at issue as approved through a "New Drug Application" (NDA #018415). The IRE also received information from the TPA regarding the marketing category history of each NDC, which included NDC effective dates, marketing category classification, and marketing category start and end dates. The information provided showed that on January 1, 2011, furosemide 20 mg (NDCs 67253-0540-10 and 67253-0540-11) and furosemide 40 mg (NDCs 67253-0541-10 and 67253-0541-11) were listed with a marketing category code

[3] Available at http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm.
[4] Available at http://www.accessdata.fda.gov/scripts/cder/ndc-old/default.cfm.
[5] Available at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

"NDA" effective January 30, 2011, and had an open-ended termination date (December 31, 9999). Additionally, the TPA indicated that as of January 1, 2011, furosemide 20 mg was on the NDC Brand Generic table as being listed with a marketing category code of NDA.

The IRE noted that for inclusion in the Discount Program, a drug must be approved through a New Drug Application or "NDA" or Biological Licensing Agreement or "BLA" and that the record showed that it was clear that the drugs at issue were classified as approved under an NDA. The IRE pointed out that CMS relies on the FDA to identify applicable drugs in the Discount Program, and under CMS rules, it is the manufacturer's responsibility to ensure that all of its drug products are properly listed on the FDA New NDC Directory.[6] Additionally, CMS provided guidance for situations where the drug product has never been listed on the FDA's New NDC Directory on or after January 1, 2011, and advised that, as of July l, 2011, "'PDE edits for the coverage gap discounts are based upon the marketing category specified in the FDA Orange Book for NDCs listed only on the FDA Old NDC Directory."[7]

The IRE found that the manufacturer failed to demonstrate that all of the drug reference numbers (DRNs) at issue were not applicable drugs for purposes of the Discount Program. The IRE found that the drugs at issue were not listed in the New NDC Directory. However, the marketing categories of the drugs at issue were listed as approved under an NDA in both the Orange Book and the Old NDC Directory. The TPA provided information, that effective January l, 2011, the drugs at issue were listed with a marketing category as NPAs. Thus, the IRE found that on the applicable dates of service (January 19, 2011 through September 15, 2011), all of the drugs at issue were approved under an NDA. For these reasons, the IRE denied DAVA's appeal and found that the drugs at issue were applicable drugs within the parameters of the Discount Program, and were appropriately billed for the coverage gap discount dollars associated with the NDCs and the corresponding DRNs under §§ 1860D-43 and 1860D-14A of the Act.

COMMENTS

DAVA requested review and included an informal electric mail from regulatory counsel at the FDA to support its argument that application #018415 is not an NDA. The regulatory counsel's electronic mail explains that application #018415 was approved in July 1982, under the "'Paper NDA", and was 'administratively converted" into an ANDA after passage of the 1984-Hatch-Waxman amendments that created the ANDA approval pathway. The counsel explained, if a brand name drug, such as Lasix, (furosemide) was

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[6] *See* CMS Memorandum, dated December 17, 20 I 0, entitled "Medicare Coverage Gap Discount Program Guidance."

[7] *See* CMS Memorandum, dated September 12, 2011, entitled "'Update on Part D National Drug Code Edits" at p.5.

approved after 1962, an ANDA could not be submitted for a generic copy prior to the law change in 1984. In short, a paper NDA was approved under the NDA provision of the statute at section 505(b) at that time, but rather than containing original new studies, the safety and efficiencies portion of the application consisted of copies of studies and reports available from published literature.

CM submitted comments stating that the official FDA information, relied on by CMS and Part D sponsors for making the applicable drug determination in accordance with CMS Discount Program guidance, identified the (NDCs associated with DAVA's furosemide products at issue as being approved under an NDA. Therefore, the drugs met the criterion of applicable drugs under the Discount Program. Thus, CM stated, the TPA and IRE were correct in determining that DAVA failed to demonstrate that the NDCs do not meet the definition of an applicable drug.

CM stated that an applicable drug is a covered Part D drug that in the case of a drug product, is approved under an NDA under §505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA), and that in this case, the four NDCs identifying DAVA's furosemide products are all listed with application #018415. DAVA does not dispute that this is the correct application number associated with the NDCs at issue, but does dispute that this application number represents an NDA. CM pointed out that, in accordance with CMS guidance issued December 17, 2010, CMS relies on the FDA to identify applicable drugs in the Discount Program. Because DAVA had not electronically listed their NDCs associated with application #018415, CMS relied on the FDA Orange Book to determine that it was an NDA.

CM noted that DAVA in its appeal to the CMS Administrator, included an informal electronic mail from regulatory counsel at the FDA to support its argument that application #018415 is not an NDA. The electronic mail refers to application #018415 as an ANDA and explains that it was approved under an NDA in 1982, and was "administratively converted" into an ANDA after passage of the 1984-Hatch-Waxman amendments that created the ANDA approval pathway. CM argued that this administrative action is irrelevant to the determination that DAVA's furosemide products are applicable drugs under the Discount Program. Section 1860D-14(A)(g)(2) of the Social Security Act makes it clear that a Part D drug approved under an NDA pursuant to §505(b) of the Federal Food, Drug and Cosmetic Act (FDCA) is an applicable drug under the Discount Program and, therefore, subject to coverage gap discounts. CM pointed out that the correspondence did not dispute that application #018415 is an NDA, and that it actually confirms that application #018415 was approved under the NDA provisions pursuant to §505(b) of the FDCA and not under the ANDA provisions pursuant to §505(j). Additionally, nothing in the correspondence shows that the NDA designation in the FDA Orange Book was, or is, in error.

Thus, CM concluded that because DAVA failed to demonstrate at any level of the dispute and appeal processes that its NDCs for furosemide do not meet the definition of an "applicable drug" under the Discount Program in accordance with the statute and its Discount Program Agreement. Thus, the Administrator should uphold the IRE's decision that DAVA was appropriately billed for the coverage gap discount payments.

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) (Pub. Law 108-173) amended the Social Security Act to, inter alia, 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 §l 860D-14A to the Act. Under the program, the ACA made manufacturer discounts available to applicable Medicare beneficiaries receiving "applicable drugs" 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 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.[8] 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.[9] Each Part D sponsor calculates the applicable discount for an applicable coverafte gap claim and advances the discount to the beneficiary on behalf of the manufacturer.[10] 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

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

[9] 42 C.F.R. § 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.

[10] 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 even submission process.

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-l4A(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 Manufacturer 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 Review Entity.[11]

With respect to the determination of an "applicable drug", an applicable drug, as defined in §l860D-l4A(g)(2) of the Act, is a covered Part D drug that is either approved under a "New Drug Application" or "NDA" under §505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA)[12] or, in the case of a biologic product, licensed under §351 of the Public Health Service Act (BLA).[13] New Drug Applications or NDAs are set forth under §505(b) of the FFDCA. Section 505(b)(l) provides the traditional NDA route with full reports of investigations of safety and effectiveness and §505(b)(2) provides an NDA with full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. In contrast, an "Abbreviated New Drug Application" or ANDA process is set forth at §505(j) and provides for an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved product.[14]

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[11] 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.

[12] *See also* 21 USC§ 355.

[131] *See also* 42 USC§ 262.

[14] *See also* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucmO69962.htm

Consistent with the law, the regulation at 42 C.F.R. §423.100 states that an:

> *Applicable drug* means a Part D drug that is—
>
> (1)(i) Approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA); or
>
> (ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such section 351); and
>
> (2)(i) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in;
>
> (ii) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in; or
>
> (iii) Is provided to a particular applicable beneficiary through an exception or appeal for that particular applicable beneficiary.

Further, each manufacturer enters into a Manufacturer Agreement with CMS.[15] The Manufacturer agreement similarly defines the terms "applicable drugs" consistent with in

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http://www.fda.gov/downloads/Drugs/Guidances/ucm079345.pdf (Draft guidance for comment), which explains the background of §505(b)(2) and (j) and Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). ("This provision expressly permits FDA to rely, for approval of an NDA, on data not developed by the applicant. Sections 505(b)(2) and (j) together replaced FDA's paper NDA policy, which had permitted an applicant to rely on studies published in the scientific literature to demonstrate the safety and effectiveness of duplicates of certain post-1962 pioneer drug products (see 46 FR 27396, May 19, 1981). Enactment of the generic drug approval provision of the Hatch-Waxman Amendments ended the need for approvals of duplicate drugs through the paper NDA process by permitting approval under 505(j) of duplicates of approved drugs (listed drugs) on the basis of chemistry and bioequivalence data, without the need for evidence from literature of effectiveness and safety. Section 505(b)(2) permits approval of applications other than those for duplicate products and permits reliance for such approvals on literature or on an Agency finding of safety and/or effectiveness for an approved drug product.")

[15] See n. 1. A copy of the ag\eement was posted at the CMS website at:

sections 1860D-1 through 1860D-43 of the Act as interpreted and applied herein and that "Covered Part D drug" has the meaning as set forth in 42 CFR 423.100.[16] In addition, the Manufacturer Agreement defines the responsibilities of the manufacturers including that:

> In order for Part D coverage to be available for covered Part D drugs of a Manufacturer, the Manufacturer agrees to the following:
> …
> (j) To electronically list and maintain an up-to-date electronic FDA registration and listing of all NDCs so that CMS and Part D sponsors can accurately identify applicable drugs (as defined in section I.(b) of this agreement).

The Manufacturer Agreement explains that the "Prescription Drug Event" or "PDE" refers to a summary record that documents the final adjudication of a Part D dispensing event. The invoice is calculated by CMS (or the TPA) based upon PDE information reported to CMS by the Part D sponsor.[17]

The guidance for the editing of prescription drug event data submissions was set forth in the "Prescription Drug Event (PDE) Edit" Guidance, dated September 24, 2010[18]. For that period, the "Drug Data Processing System" included an on-line PDE editing used to evaluate data on an incoming PDE and confirm its consistency with other data reported on the same PDE as well as data reported on selected editing tables. Notably, it uses data from external resource sources to validate National Drug Codes. A condition for exclusion of a PDE as payable under the Gap Discount Program was included in the data editing as edit no. "867" described as "NDCs not identified as NDA or BLA by the FDA." Under this edit code, where the "FDA does not designate this drug as NDA or BLA" the particular identified PDE "is ineligible for the coverage gap discount." Thus, as part of the PDE data submission and invoicing process, CMS incorporated edits on the PDEs

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http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/CGDPMfrAgrmtOriginal.pdf

[16] The Manufacturing Agreement also explains that the: " 'Labeler Code' means the first 5 digits in the 11-digit national drug code (NDC) format that is assigned by the FDA and identifies the Manufacturer" and that the 'National Drug Code (NDC)' means the identifying prescription drug product number that is registered and listed with the Food and Drug Administration (FDA). For the purposes of this Agreement, the NDC refers to either the 9-digit (inclusive of 5 digit labeler code and 4 digit product code) or 11-digit (inclusive of 5 digit labeler code, 4 digit product code, and 2 digit package size code) NDC, as designated by the Secretary."

[17] Exhibit B of the Manufacturer Agreement explains the "PDE Data Elements Available Upon Audit Only."

[18] Effective January 1, 2011.

received from Part D sponsors to ensure that Part D Sponsor discount all, and only, "applicable drugs."

In the May 21, 2010 "Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance" CMS reiterated the statutory definition of "applicable drugs" and reminded Part D sponsors that they must identify those NDCs for covered Part D drugs that are approved under NDAs or licensed under BLAs. CMS stated it would continue to work with the FDA to make this information more transparent and readily available to Part D Sponsors to assist with making these determinations.[19]

Notably, CMS also stated in response to comments that:

> Neither section 3301 Affordable Care Act, nor CMS final guidance make any distinction between multiple source drugs or authorized generics drugs approved under new drug application [NDA] verses any other applicable drug. We believe the definition of applicable drug includes all drugs approved under NDAs, and therefore all such drugs are subject to the discount if covered under a manufacturer discount agreement.[20]

CMS also promulgated Guidance, issued December 17, 2010, to Pharmaceutical Manufacturers, stating in Section 5 that:

> CMS relies on the FDA to identify applicable drugs in the Discount Program.
>
> Manufacturers must ensure that all of their drug products (i.e. national drug codes (NDCs)) are properly listed on the FDA NDC Directory. Manufacturers must electronically list and maintain up-to-date electronic FDA registrations and listings of all NDCs, including the timely removal of discontinued NDCs from the FDA NDC Directory. Accurate NDC listings will enable CMS and Part D sponsors to accurately identify applicable drugs and, accordingly, updates to the FDA NDC Directory must precede NDC additions made to commercial electronic databases used for pharmacy claims processing. Manufacturers will not be able to successfully appeal invoiced amounts based on inaccurate or out-of-date, FDA NDC Directory listings without documentation that the manufacturer notified the FDA of an error, or requested that an out-dated NDC be removed from the Directory, in

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[19] *See* "Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance," dated May 21, 2010 at 17.

[20] *See* "Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance," dated May 21, 2010 at 4.

> order to show that it was not a result of manufacturer non-compliance with the Discount Program requirement.
>
> In addition, CMS expects manufacturers to maintain up-to-date listings with the electronic database vendors for which they provide their NDCs for pharmacy claims processing. Only the manufacturers know the last-lot expiration dates for their NDCs and therefore, the manufacturers are responsible for ensuring that these electronic database vendors are prospectively notified when NDCs no longer represent products that are still available on the market. A manufacturer's failure to provide appropriate advance notice to electronic database vendors may result in the manufacturer's being responsible for discounts after the last-lot expiration date unless the manufacturer can document that it provided such appropriate advance notice to the database vendors, or the manufacturer has provided advance notice to the FDA of the marketing end date.[21]

CMS also 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 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.[22] Manufacturers bear the burden of proof in meeting these standards. CMS explained that: "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 occurred."[23] Further, CMS again explained that:

> NDC Not on Market
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> An "NDC Not on Market" appeal means that the last lot for that NDC has expired. The IRE will further review and validate "NDC Not on Market" appeals if the manufacturer demonstrates that the date of service postdates the last- lot expiration date for the NDC and that the manufacturer had timely reported that expiration date to the Food and Drug Administration FDA). We remind manufacturers that they are required to maintain updated electronic FDA listing of all NDCs, including the timely removal of NDCs no longer on the market from the FDA NDC Directory. Manufacturers should refer to section 5 of the December 17, 2010 guidance for additional information on their responsibility to maintain up-to-date listings with both

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[21] *See* "Medicare Coverage Gap Discount Program Guidance," dated December 17, 2010.
[22] *See,* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011.
[23] *See,* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011 at 2.

> the FDA and electronic database vendors (e.g., First DataBank, Medispan) used for pharmacy claims processing.[24]

On March 5, 2012, CMS provided additional industry guidance for the Discount Program "Medicare Coverage Dispute Resolution." 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 Expiration Date," "Early Fill," "Marketing Category Not a Biologic License Application (BLA) or New Drug Application (NDA)" and "Other."[25] The March 5, 2012 Guidance summarized the existing program practices and provided further clarification of CMS' expectations regarding dispute submissions based upon a detailed analysis of the data collected as part of the dispute resolution process for PDEs submitted for the 2011 coverage year" CMS explained that:

> Marketing Category is Not NDA or BLA (D09)
>
> The CGDP makes manufacturer discounts available to applicable Medicare beneficiaries receiving applicable drugs while in the coverage gap. A dispute that is filed on the basis that the marketing category is neither a New Drug Application (NDA) nor a Biologic License Application (BLA) means that the manufacturer believes that the drug product is not an applicable drug due to the marketing category of the product on the date of service and that the product is therefore ineligible for the coverage gap discount.
>
> On September 12, 2011, CMS issued guidance entitled "Update to Part D National Drug Code Edits" which describes the PDE editing logic that it uses to identify applicable drugs subject to the discount. As of July 1, 2011, PDE edits for coverage gap discounts are based upon the marketing category specified in the new FDA NDC Directory, not the FDA Orange Book. The exception is for NDCs listed only on the old FDA NDC Directory, in which case, the PDE edits for the coverage gap discount are based on the marketing category specified in the FDA Orange Book. If the NDC is listed on both the new FDA NDC Directory and the old FDA NDC Directory, CMS will rely on the marketing category specified in the new NDC Directory, not the FDA Orange Book.

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[24] *See*, Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011 at 3.

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

> In June 2011, the FDA began posting the new FDA NDC Directory.4 The new Directory identifies only those NDCs that have been electronically listed with the FDA and includes data fields such as marketing category, marketing start date, and marketing end date. While the FDA only updates the new Directory, the FDA also posted a final old NDC Directory on June l, 2011, that includes both electronically listed and paper listed NDCs. The CMS system receives updates from the FDA eList on a monthly basis.
>
> When performing edits to determine whether an NDC is an applicable drug, the CMS system first checks the eList for the NDC and uses the marketing category listed. If the drug is not on the eList, the editing logic then checks the old NDC directory for the application number to obtain the marketing category from the FDA Orange Book. Once the source of the marketing category information is determined, the CMS system identifies the marketing category and checks that the date of service for the PDE falls between the Marketing Category Start Date and the Marketing Category End Date.
>
> When the TPA receives a dispute on the basis that the marketing category is neither NDA nor BLA, it confirms the marketing category at the time of submission and editing for the date of service in question. If the research into the dispute shows the marketing category to be NDA or BLA at the time of PDE submission for the DOS, then the dispute is denied.
>
> CMS relies on the FDA listing data to identify applicable drugs in the CGDP. Manufacturers must ensure that all of their drug products are properly listed on the FDA NDC Directory. Manufacturers will not be able to successfully dispute invoiced amounts based on inaccurate or out-of-date FDA NDC directory listings without documentation that the manufacturer notified the FDA of an error. Manufacturers that fail to update their information in a timely fashion and, as a result, are billed for discounts based on incorrect information, must pay the amounts billed, and CMS will not consider such failures to be grounds for successful dispute of invoiced amounts. (Emphasis added.)

In explaining the supporting data for such an appeal based upon "Marketing Category is not NDA or BLA," CMS reaffirmed that:

> Supporting evidence should demonstrate that:
> - The FDA was notified of a change or error in the FDA Directory; and/or
> - That updates to the FDA Directory were made prior to the DOS and processing date of the PDE.

CMS acknowledged confusion with respect to how some manufacturers were filing appeals noting that:

> Not Part D Covered Drug (D03)
> We have observed confusion among manufacturers regarding the intent of this dispute reason. 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 on the basis that the drug is potentially a non-applicable CGDP drug, but otherwise would be covered under Medicare Part D. Manufacturers that dispute a discount payment on the basis that the drug is a Part D covered drug but is not eligible to receive the discount, should use the reason code of D09 Marketing Category is Not NDA or BLA. We have also observed that this dispute reason code has also been used to file disputes on the basis of the last lot expiration date. For these disputes, manufacturers should use reason code D07 Last Lot Expiration Date.

CMS further explained in guidance issued September 12, 2011 regarding "Updates on Part D National Drug Code Edits"[26], that with recent changes to the FDA NDC Directory, CMS was "providing this update to explain how CMS is using, and plans to use, publically available FDA information (or lack of FDA information) when establishing PDE edits for Discount Program." CMS stated that:

> In June 2011, the FDA began posting the new FDA NDC Directory at http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm. The new Directory identifies only those NDCs that have been electronically listed with the FDA and includes additional data fields such as marketing category, marketing start date, and marketing end date. While the FDA will only update the new directory, the FDA also posted a final old directory on June 1, 2011, that includes both electronically listed and paper listed NDCs. This old directory will no longer be updated with NDC additions, deletions or changes.
>
> With the goal of transitioning to the new FDA NDC Directory as the sole official source for NDCs for drug products on the market that are required to be listed with the FDA, including the source for the marketing category, marketing start date and marketing end dates, CMS will establish PDE edits for the Discount program based upon the new FDA NDC Directory downloadable files using the following logic:

[26] *See* CMS Memorandum, dated September 12, 2011, entitled "Update on Part D National Drug Code Edits."

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> As of July 1, 2011, PDE edits for the coverage gap discounts are based upon the marketing category specified for the new FDA NDC Directory, not the FDA orange book, except that PDE edits for the coverage gap discounts are based upon marketing category specified in the FDA Orange Book for NDCs listed ONLY on the old FDA NDC Directory. (Emphasis added.)

The Orange Book is the popular short title for the FDA publication "Approved Drug Products with Therapeutic Equivalent Evaluations." The Orange Book, which derives its name from its original publication color, identifies drug products approved on the basis of safety and effectiveness by the FDA under section 505 of the Federal Food, Drug, and Cosmetic Act.[27] The Electronic Orange Book (EOB) includes: New Drug Application (NDA) approvals in the EOB month they were approved (NDA application numbers are preceded with "N"); Abbreviated New Drug Application approvals (ANDA or Generic) as of the date of the daily update (Generic application numbers are preceded with "A"); and all product changes received and processed as of the monthly update date (discontinued products will be process as of the date of publication).[28]

In addition to the Orange Book, a reference for approved drugs is the old and new FDA National Drug Code or "NDC" Directories. As noted in the manufacturing agreement definitions, drug products are identified and reported using a unique, three-segment number, called the National Drug Code or NDC, which serves as a universal product identifier for drugs. The FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is updated daily.

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[27] See http://www.fda.gov/Drugs/DevelopmentApprovalProces/ucm079068.htm ("Orange Book Preface" Food and Drug Administration, Center for Drug Evaluation and Research, "Approved Drug Products with Therapeutic Equivalence Evaluations" 34th Edition)
See http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm ("Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)- About the Orange Book")
See http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm ("Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations")(Searchable Electronic Orange Book)

[28] http://www.fda.gov/Drugs/lnformationOnDrugs/ucm114166.htm ("Frequently Asked Questions on the Orange Book")
http://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm ("Orange Book Preface" Food and Drug Administration, Center for Drug Evaluation and Research, "Approved Drug Products with Therapeutic Equivalence Evaluations" 34th Edition)

The information submitted as part of the listing process, the NDC number, and the NDC Directory are used in the implementation and enforcement of the Act. The FDA explained that The Drug Listing Act of 1972 requires registered drug establishments to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. With respect to the new FDA NDC directory, the FDA explained that:

> For four decades, the NDC Directory has been published by FDA, derived from information submitted to the agency as part of drug listing requirements under section 510 of the FD&C Act, 21 USC 360.
>
> Section 510(p) of the FD&C Act (21 USC 360(p)) now requires registration and listing information for human drugs to be submitted electronically, unless a waiver is granted. In keeping with this provision, in June of 2009, the FDA stopped accepting hardcopy/paper submissions of drug registration and listing information..., and began accepting only electronic submissions..... This data is processed and stored within an FDA internal software system known as eLIST and eDRLS.
>
> The data from the older paper-based Drug Registration and Listing System (DRLS) was not migrated to these electronic systems.. Although FDA began accepting new listing submissions only in electronic form in June 2009, since that date, FDA continued to publish the NDC Directory based on information in DRLS, which has been maintained in parallel until 2011 using data submitted to eLIST. eLIST and eDRLS, however, continue to grow over time as companies list new products and update existing records. The FDA believes that sufficient time has passed since the establishment of eLIST and eDRLS for it to now serve as the data source for the NDC Directory.
>
> On June 1, 2011, the NDC Directory switched its data source from the older DRLS system to eLIST and later to eDRLS. Starting June 1, 2011, only drugs for which electronic listings (SPL) have been submitted to FDA are included in the NDC Directory. Drugs for which listing information was last submitted to FDA on paper forms, prior to June 2009, are included on a separate file and will not be updated after June 2012.[29]

The FDA further explained that:

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[29] Explanation of the new and old "National Drug Code Directory" at http://www.fda.gov/drugs/informationondrugs/ucm142438.htm

> Some NDCs that cannot be found in the newer eLIST and eDRLS version of the Directory may potentially be found in this older version of the NDC Directory.[30]

Finally, consistent with the guidance and statutory scope of the Discount Program, CMS has since codified certain portions of the Manufacturer Agreement pursuant to the final rule[31] stating in the preamble that:

> To permit CMS and Part D sponsors to accurately identify applicable drugs, we proposed to codify the requirement set forth in the Discount Program Agreement that manufacturer's electronically list and maintain an up-to-date electronic listing of all NDCs of the manufacturer, including the timely removal of discontinued NDCs, in the FDA NDC Directory. We believe this requirement will help ensure that all currently marked applicable drugs are subject to the applicable discount and that only currently marketed applicable drugs are subject to the discount. Because manufacturers know the regulatory and marketing status of their products, they are in the best position to make this information available to Part D sponsors and CMS. We believe maintaining an up-to-date FDA electronic listing provides the most the FDA electronic registration and listing system to comply with other FDA requirements. In this final rule with comment period, we are making a technical correction to this requirement by specifying that manufacturers provide timely information about discontinued drugs to enable the publication of accurate information regarding what drugs, identified by NDC, are in current distribution. This language replaces the requirement that manufacturers timely remove discontinued NDCs in the FDA NDC Directory because we realized that it is the FDA that makes the

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[30] Explanation of the new and old "National Drug Code Directory" at http://www.fda.gov/ drugs/informationondrugs/ucm142438.htm
The searchable "New NDC Directory" is at http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm

[31] 77 Fed. Reg. 22072 (April 12, 2012)(Final rule)(Centers for Medicare & Medicaid Services 42 CFR Parts 417, 422, and 423 Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes)[31] 76 Fed. Reg. 63018 (October 11, 2011) (Proposed rule) (Centers for Medicare & Medicaid Services 42 CFR Parts 417, 422, 423, and 483 Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Proposed Changes; Considering Changes to the Conditions of Participation for Long Term Care Facilities).

> determination to remove NDCs based upon information provided by the manufacturer.[32]

Thus, the regulation at 42 CFR 423.2315 codified the manufacturer agreement requirements and stated, in relevant part, that:

> a) General rule. The Medicare Coverage Gap Discount Program Agreement (or Discount Program Agreement) between the manufacturer and CMS must contain the provisions specified in paragraph (b) of this section, and may contain such other provisions as are established in a model agreement consistent with section 1860D-14A (a)(l) of the Act.
>
> (b) Agreement requirements. The manufacturer agrees to the following:
>
> ***
>
> (7) Electronically list and maintain up-to-date electronic FDA listings of all NDCs of the manufacturer, including providing timely information about discontinued drugs to enable the publication of accurate information regarding what drugs, identified by NDC, are in current distribution.

Thus, the official FDA drug listings as set forth in the New NDC Directory or, as applicable, in the Old NDC Directory and Orange Book, are relied upon by CMS and Part D sponsors for making the applicable drug determinations in accordance with CMS Discount Program Guidance, the Manufacturing Agreement, and the controlling law.

In this case, the record shows that the NDCs associated with DAVA's furosemide products at issue were approved under an NDA and, therefore, met the criteria of an applicable drug under the Discount Program for the period at issue. Because the drugs at issue were not listed in the New NDC Directory, the reviewing entity properly relied upon the marketing categories of the drugs as listed in the Orange Book and the Old NDC Directory. The record shows that effective January 1, 2011, the drugs at issue were listed with a marketing category of NDA

In particular it was not disputed that the drugs at issue had an application #018415. The New NDC Directory did not list application #018415. The Old NDC Directory and Orange Book both listed the application #018415 as approved through a "New Drug Application" (NDA #018415). The IRE received confirmation from the TPA regarding the marketing category history of each NDC, which included NDC effective dates, marketing category classification, and marketing category start and end dates. The

[32] 77 Fed. Reg. 22072 at 22084.

Information provided showed that for the period at issue, on January 1, 2011, furosemide 20 mg (NDCs 67253-0540-10 and 67253-0540-11) and furosemide 40 mg (NDCs 67253-0541-10 and 67253-0541-11) were listed with a marketing category code "NDA" effective January 30, 2011, and had an open-ended termination date (December 31, 9999). Additionally, the TPA found that as of January 1, 2011, furosemide 20 mg was on the NDC Brand Generic table as being listed with a marketing category code of NDA. The IRE subsequently determined that on the applicable dates of service, January 19, 2011 through September 15, 2011, all of the drugs at issue were subject to NDAs. The Administrator finds that the record supports these findings.

As set forth above, for inclusion in the Discount Program, a drug must be approved through a NDA or BLA. The record demonstrates that the drugs at issue were classified as approved under an NDA. CMS relies on the FDA to identify applicable drugs in the Discount Program, and under CMS rules, it is the manufacturer's responsibility to ensure that all of its drug products are properly listed on the FDA NDC Directory.[33] Where the drug product has never been listed on the new FDA NDC Directory on or after January 1, 2011, CMS stated that, as of July 1, 2011, prescription drug event edits for the coverage gap discounts are based upon the marketing category specified in the FDA Orange Book for NDCs listed only on the old FDA NDC Directory.[34] Therefore, the Administrator finds that the IRE was proper in finding that DAVA failed to demonstrate that the third quarter, 2011 invoice for coverage gap discounts was incorrect in accordance with the Discount Program Agreement and applicable law.[35] The drugs at issue were "applicable drugs" under Coverage Gap Discount Program and were appropriately billed for the coverage gap discount dollars associated with the NDCs and the corresponding DRNs under §§ 1860D-43 and 1860D-14A of the Act.

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[33] *See* CMS Memorandum, dated December 17, 2010, entitled "Medicare Coverage Gap Discount Program Guidance."

[34] *See* CMS Memorandum, dated September 12, 2011, entitled "Update on Part D National Drug Code Edits"·at 5.

[35] In addition, as CMS explained in the March 5, 2011 Guidance, with respect to an appeal under "Not Part D Covered Drug (003)", 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 on the basis that the drug is potentially a non-applicable Covered Gap Discount Drug, but otherwise would be covered under Medicare Part D. Accordingly this would not be a proper basis for the Manufacturer's appeal in this case as originally set forth to the TPA, but rather "Marketing Category is not New Drug Application or Biological Licensing Agreement" as set forth to the IRE as the modified basis for the appeal.

DECISION

In accordance with the foregoing, the Administrator hereby upholds the decision of the Independent Review Entity.

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

Date: 5/30/14

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES
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Office of the Attorney Advisor

MAY 2 8 2014

Ms. Annette McLoughlin
Pfizer, Inc.
235 E. 42nd Street
New York, NY 10017-5755

Re: Pfizer, Inc., Appeal CGDP0000252011

Dear Ms. McLoughlin:

Enclosed is a copy of the Administrator's decision in the above case affirming 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 CASE OF:	*	**Appeal No. CGDP0000252011**
	*	
Pfizer, Inc.,	*	
	*	
	*	**Date: December 22, 2011**
	*	
	*	

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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 Pfizer, Inc. (Pfizer or the Manufacturer) timely requested review of the IRE's decision. The Centers for Medicare, Medicare Drug Benefit and C&D Data Group (CM) submitted comments requesting that the Administrator affirm the IRE's decision. 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/CGDPMfrAgrmtOriginal.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.

ISSUE AND IRE DECISION

In this appeal before the Administrator, the issue involves whether the IRE properly determined that Pfizer, Inc. failed to demonstrate that the first quarter 2011 invoice was in error with respect to the applicable coverage gap discounts for Revatio 20mg for DRNs 00069000000000001690 and 00069000000000130409.

The IRE examined the information submitted by Pfizer, the Third Party Agency (TPA) dispute review records, and information the TPA requested from the Part D sponsor during the IRE appeal process. The IRE determined that the information it received from the Part D Sponsor reaffirmed the information provided during the TPA dispute process. The Part D Sponsor validated that the drugs were dispensed appropriately, billed at the correct price, and provided to the beneficiary at the proper discount. With respect to Revatio 20 mg. DRNs 00069000000000001690 and 00069000000000130409, the Manufacturer initially argued that the "daily recommended dose is three tab according to prescribing information" which was denied by the TPA. On appeal to the IRE, the Manufacturer argued that the "costs seems excessive." The dispute file received from the TPA showed that the matter before the TPA was appealed as Dispute Code 04 "Excessive Quantity" as the "daily recommended dose is three tabs according to prescribing information." The IRE requested information from the Part D Sponsor verifying the drug dispensing information for the DRNs. The IRE reviewed the information provided with respect to its argument that the "cost seems excessive." The Manufacturer did not provide further explanation to support this assertion. However, the Manufacturer has the burden of proof to demonstrate that the gap discount was excessive or likely in error. The IRE denied the appealed DRNs finding that the dollars invoiced did not represent excessive gap discounts and, thus, the invoiced amount was appropriate and within the purview of the Discount Program.

COMMENTS

Pfizer requested review of the IRE's decision based on the High Price of Drug/Excessive Gap Discount for DRNs 00069000000000001690 and 00069000000000130409 and attached a spreadsheet that shows the estimated cost of the prescription, 50 percent of the cost, as well as the requested rebate amount in each case, and that what is being requested (and what was paid on) exceeds the applicable percentage (50 percent) that is payable under the Medicare Coverage Gap Discount Program Agreement..

CM commented regarding two of the disputes concerning discounts for Revatio 20 mg tablets. CM submitted comments stating that Pfizer contended that the discount amounts for Revatio shown in the invoices were excessive in that they were larger than the amount Pfizer anticipated based on its estimate of the cost of a 30 day

supply of Revatio at $2,702.39. Pfizer calculated that it would be liable for the 50 percent discount from that price, or $1,351.20. CM first commented that Pfizer failed to explain how it determined the estimated cost of the Revatio which is required under the May 2011 Appeals Guidance based on High Price of the Drug/Excessive Gap Discount. CM commented that manufacturers are required to provide reliable information to demonstrate that the gap discount amount is excessive and likely in error given the fact that the manufacturer does not have access to the actual negotiated price of a drug between a Part D sponsor and a pharmacy. Moreover, CM stated that the invoices that manufacturers received from the TPS do not contain the total ingredient cost of the prescription to which the discount is applied. According to Section V(c) of the Agreement, total ingredient cost of the prescription information would only be provided to manufacturers upon its request of an audit.

In addition, CM commented that for the appeal at issue, the actual total ingredient cost of the Revatio prescription was $2,837.53. Fifty percent of the actual total ingredient cost of Revatio is $1,418.77. The difference between $1,351.20 and $1,418.77 is $67.57 or 2.38 percent of the total ingredient cost of the drug. CM commented that this small differential clearly does not meet the standard that is necessary to support an appeal to the IRE and does not demonstrate that the gap discount amount is excessive and likely in error.

CM also commented that since Part D sponsors negotiate prices with their contracted network pharmacies, CMS looked at the total ingredient cost for Revatio in January, 2012 (2011 data was no longer available), based on the date Part D sponsors provide for the Medicare Plan Finder or MPF web tool. CM stated that the MPF is an on-line tool available to the general public that allows beneficiaries to input their exact drugs and compare Medicare Part D drug plans. The MPF showed that in January 2012, the lowest total ingredient cost of a 30 day supply of 180 tablets for Revatio was $2, 129.34 and the highest total ingredient cost of a 30 day supply of 180 tablets for Revatio was $3,869.15. CM commented that manufacturers can obtain this type of pricing information from CMS on a quarterly basis by purchasing a Public Use File (PUF). CM stated that the information in the PUF provides plan level average monthly costs for formulary Part D drugs and represents the information the Part D sponsor provide to the Medicare Plan Finder.

In summary, CM stated that Pfizer failed to demonstrate at any level of the dispute and appeal processes that the invoiced discount amounts for Revatio were incorrect. Based on the information provided in the IRE decisions, CM requested that the Administrator uphold the IRE's decision that Pfizer was appropriately

billed for Quarter One coverage gap discount payments associated with the two DRNs subject to the instant appeal.

DISCUSSION

The entire record furnished by CM has been examined, including any correspondence, position papers, exhibits, and subsequent submissions. All comments received timely are included in the record and have been considered.

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)[2] amended the Social Security Act (the Act) to create *inter alia*, 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 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

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[2] Pub. Law 108-173.

[3] 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).

[4] *See:;*. CMS Memorandum "Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance" issued on May 21, 2010.

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 or 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)(1)(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 part administrator; it has the right to appeal to the Independent 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.

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 bases upon which a manufacturer may challenge a discount payment: National Drug

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[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 based on the negotiated price with the pharmacy and reports the discount payment amount to CMS through its normal Part D prescription drug event submission process.

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

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.[8] Manufacturers bear the burden of proof in meeting these standards.

The May 31, 2011 appeals guidance noted that there were several primary dispute reasons that may reasonably be appealed. CMS clarified its expectations of manufacturers as to what must be demonstrated for these appeals to justify further review and validation by the IRE. Relevant to this appeal, 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.
>
> 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 appeal quantities that represent less than three times the maximum FDA labeled dose, or for any quantity-related appeal if there is no maximum FDA labled daily dose, will need to demonstrate that the dose represents a severe threat to the health of beneficiaries, is inconsistent with the packaging of the product, or otherwise represents an unlikely dose in the Medicare population.[9]

In addition, relevant to this case, the guidance 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

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

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

> 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.[10]

The CMS Discount Program appeals guidance specifically stated that, "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."[11] 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."[12] 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. 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." 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]

Pursuant to a March 5, 2012 Dispute Resolution Guidance memorandum, 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 Expiration Date, Early Fill, Marketing Category Not a Biologic License Application (BLA) or New Drug Application (NDA) and Other.[14]

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

[11] *See,* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, at 2.

[12] *Id.* at 3.

[13] *See,* Medicare Coverage Gap Discount Program - Dispute Resolution, dated March 5, 2012, and Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011 at 2.

[14] *See, e.g.* Medicare Coverage Gap Discount Program - Dispute Resolution, dated March 5, 2012, at 1-2.

The March 5, 2012 memorandum again emphasized that CMS will deny disputes if the discount payment is accurately calculated, even if the dispensing event may not have been clinically appropriate. The dispute 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. In explaining the basis for disputes generally, CMS explained that manufacturers must explain why they believe that the invoiced gap discount amount is likely in error. The Dispute Resolution Guidance 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 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.[15]

The Attached "Summary of Dispute Submission Guidance by Reason Code" set forth the expected supporting Documentation stating for "'Excessive Quantity" that:

> REQUIRED:
> The ADDITIONAL INFORMATION field should provide supporting evidence that:
> - The quantity is inconsistent with the packaging of the product;
> - The quantity is unlikely in the Medicare population;
> - The gap discount is based on an inaccurate calculation; and/or,
> - The gap discount was based upon inaccurate data that does not represent the dispensing event that occurred.
>
> Please provide the proprietary benchmark used to identify excessive quantity.

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[15] *See,* Medicare Coverage Gap Discount Program Appeals Guidance, dated March 5, 2012, at. 1-2.

Moreover, the Dispute Resolution Guidance memorandum from CMS addresses disputes for high price and states:

> 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 not be file under D99[16] 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-11(i) of the Social Security Act from interfering "with the negotiations between the 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 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 points when evaluating the per unit price of a drug. Disputes should not be submitted solely based upon a calculated deviation between

[16] *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....")

> the Part D negotiated price and prices from other government programs or list prices.[17]

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.[18]

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.

In the instant appeal, Pfizer contracted with CMS to participate in the Coverage Gap Discount Program to begin in January 2011. Under the terms of the Discount Program Agreement (Agreement), Pfizer submitted labeler codes for drugs to be covered as Part D applicable drugs: One of these drugs was Revatio® (20mg tablets), labeler code 00069.[19] On April 30, 2011, Pfizer received its quarter one invoice covering discounts provided to Medicare Part D beneficiaries in the coverage gap from January 1, 2011 through March 31, 2011. The total invoice was for $1,050,760.80.[20] Pfizer timely paid this invoice through electronic funds transfer on June 1, 2011.

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[17] *See*, Medicare Coverage Gap Discount Program-Dispute Resolution, dated March 5, 2012 at 4.

[18] *Id.*

[19] CM Comments, Exhibit 5.

[20] CM Comments, Exhibit 6.

On June 20, 2011, Pfizer filed disputes with the TPA. Two of the disputes concerned the discounts provided for the drug Revatio. For both disputes Pfizer used the dispute reason code "D04" to indicate that the dose at issue was "Excessive Quantity," and alleged that the prescribed dose at issue was excessive. Specifically, Pfizer stated that the recommended daily dose for Revatio is "three tablets a day for a 30-day supply." The claims at issue were for 6 tablets a day for a 30-day supply.

The TPA denied Pfizer's applea under D04, Excessive Quantity.[22] Moreover, the Part D sponsor administering the Part D plan that provided the discounts confirmed that the plan's formulary subjected Revatio to prior authorization requirements before being dispensed and that the beneficiaries making these claims met the prior authorization criteria. The prior authorization criteria include confirming the beneficiary has a diagnosis of pulmonary arterial hypertension. The Part D sponsor also confirmed that the Revatio was dispensed to the beneficiaries as prescribed by their respective physicians for 180 tablets for the 30-day supply and that it was an actually occurring prescription drug event.

On September 27, 2011, Pfizer filed sixteen appeals for five National Drug Codes (NDCs) with the IRE. The appeals challenged the discounts provided for five drugs, including, in the instant case, Revatio. However, Manufacturer with respect to Revatio did not challenge the TPA dispute determination that the dosage was not excessive. (Dispute Reason Code "D04" Excessive Quantity). Pfizer appealed to the IRE that the discount amount costs for the two DRNs were excessive. (Dispute Reason Code "D06) High Price of the Drug/Excessive Gap Discount).[23]

The IRE examined the information submitted by Pfizer, the TPA dispute review record, and information it requested from the Part D sponsor during the IRE appeal process. The IRE did not request additional information from Pfizer. The IRE determined that the information it received from the Part D sponsor reaffirmed the information it had provided during the TPA dispute process. The Part D sponsor validated that the drugs were dispensed appropriately, billed at the correct price and provided to the beneficiary at the proper discount. The IRE upheld the dispute determination that Pfizer was invoiced correctly for the two Revatio claims as the Manufacturer had failed it burden of proof and failed to demonstrate that the gap discounts were excessive and likely in error.

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[21] CM Comments, Exhibit 7.
[22] *Id.*
[23] CM Comments, Exhibit 8.

Pfizer filed an appeal to the Administrator based on "High Price of the Drug/Excessive Gap Discount", arguing that the discount amounts it was charged during quarter one for Revatio 20 mg tablets for DRN 00069000000000000169 and DRN 00069000000000013049, were calculated incorrectly.[24]

Regarding the initial basis for the appeal for excessive quantities, the record shows that Pfizer 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 labeling 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.[25] In this instance, the daily recommended dose was three tablets a day or 90 tablets for a 30 day supply, whereas the dispensed amount for the respective related DRNs was 180 tablets for a 30 day supply or 6 tablets a day. Thus, the Administrator finds that the IRE properly determined that Pfizer failed to demonstrate that the invoiced amounts met the threshold criteria for an excessive quantity requiring further review.

However, Pfizer further contends in its appeal that the discount amounts calculated and invoiced for Revatio are excessive because they are in excess of the dollar amount Pfizer anticipated based on its estimate of the cost of a 30-day supply of Revatio at $2,702.39. Based on Pfizer's estimate, it would liable for the 50 percent discount in the amount of $1,351.20. However, Pfizer did not submit supporting documentation for its estimated cost of the Revatio consistent with the CMS policy guidelines and instructions. CM provided information from the prescription drug event or PDE extract that both claims at issue have an actual total ingredient cost for Revatio of $2,837.53[26] and that 50 percent of the cost is $1,418.77, which is the dollar amount that was charged to Pfizer. Therefore, the record shows confirmation that the discount was calculated correctly and was based upon accurate data that represents the dispensing events that occurred. Accordingly, the record supports a determination that the IRE was correct in denying the two Revatio related DRNs in dispute.

However, Pfizer further alleged that the difference between the calculated discount (based on the estimated cost of the prescription) versus the actual discount invoiced demonstrates that the cost is excessive. However, as noted by CM, the difference between $1,351.20 and $1,418.77 is $67.57. The amount of $67.57 is 2.38 percent

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[24] See CM Comments, Exhibit 9.

[25] *See* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, at 3. Even if such a threshold burden is met, CMS will still deny a dispute if it is subsequently confirmed, that the discount payment was accurately calculated and represented an actual dispensing event that occurred.

[26] CM Comments, Exhibit 10, Prescription Drug Event (PDE) Record Extract.

of the total ingredient cost of the drug. This small differential does not meet the standard necessary to support an appeal by demonstrating the gap discount amount is "excessive" and "likely in error."

Consequently, Pfizer failed to demonstrate at any level of the dispute and appeal process that the invoiced discount amounts for the two DRNs in dispute involving Revatio were incorrect. The Administrator affirms the IRE's decision that Pfizer was properly billed for the coverage gap discount payments associated with respect to the DRN 00069000000000001690 and DRN 0006900000000013049, for Revatio.

DECISION

The Administrator affirms the IRE's decision, in accordance with the foregoing opinion.

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

Date: 5/21/14

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services