BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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RE: Medicare Coverage Gap Discount Program Appeals Guidance

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) draft guidance on the bases for appeals under the Medicare Coverage Gap Discount Program ("Draft Appeals Guidance"). BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the world. BIO represents more than 1,100 biotechnology centers, academic institutions, state biotechnology centers, and related organizations in the United States and in more than 30 other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

BIO represents an industry that is devoted to discovering and ensuring patient access to new and innovative therapies. Many of the therapies developed by biotechnology companies target conditions that primarily affect seniors. BIO has been a strong supporter of the Medicare Part D prescription drug benefit, and believes that the Part D benefit has helped to increase patient access to critical therapies as well as ensure that patients will be able to receive and afford the treatments that best meet their needs. We appreciate CMS's efforts in implementing the Coverage Gap Discount Program.

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I. Process for Appeals

A. Timeframe for Appealing to IRE

In explaining the opportunity to seek an additional level of review from the independent review entity (IRE), CMS states that a manufacturer may only initiate this second level of review "after a disposition of a dispute submission by the [third party administrator] TPA or when the TPA does not issue a finding within 60 days."[1] This leaves open the possibility that a manufacturer may need to seek an appeal without having the benefit of a disposition from the TPA.

We urge CMS to require the TPA to issue a notice to the manufacturer within 60 days of the original dispute in circumstances where the TPA will not be issuing a disposition of a dispute within the required timeframe. This will minimize circumstances in which manufacturers must submit an appeal to the IRE in order to meet the required timeframe for filing such appeals, but the TPA then issues a disposition at the last minute which the manufacturer would not otherwise appeal. Requiring the TPA to notify a manufacturer where the 60 day timeframe will not be met will increase the efficiency of the process and reduce unnecessary consideration of appeals by the IRE.

B. Appeals to the Administrator

CMS notes that when a manufacturer appeals an IRE decision to the CMS Administrator, the Administrator "has the *discretion to elect or decline* to review the IRE decision."[2] We urge CMS to instead state that the Administrator will make a decision regarding an appeal, and provide a basis for that decision. Not doing so, we believe, is contrary to the requirements in the Model Agreement.

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[1] Draft Appeals Guidance at 2.

[2] Id. at 4.

Certainly, the Administrator may determine that the IRE's decision should be upheld, but the purpose of a third round of appeal is to provide manufacturers with a meaningful opportunity to have a dispute heard. If the Administrator is not even required to actually consider the appeal, this in essence removes a level of appeal.

Furthermore, the Draft Appeals Guidance also states that if the Administrator does not make a determination regarding review within 30 days, the IRE decision is final and binding. Again, we do not believe this is an appropriate standard. Instead, the Administrator should issue a decision on whether the IRE determination was appropriate. A manufacturer should not be deprived a level of appeal simply because the Administrator was not able to respond within 30 days.

II. Bases for Appeal

CMS states in the Draft Appeals Guidance that "the burden of proof that the submitted data is in error is on the manufacturer" and that manufacturers must demonstrate "why the information provided with the original dispute demonstrates that a discount payment is in error."[3] Given that manufacturers are provided very limited information on the invoices, we do not believe this standard is appropriate. Certainly, manufacturers should seek appeals only where the manufacturer in good faith believes that the information provided is in error, but, given the limited information provided to manufacturers under the Coverage Gap Discount Program, in many cases manufacturers may not have the information necessary to make such a demonstration. The purpose of an appeal is to allow for another level of review where a dispute has not been satisfactorily resolved; this is set forth in the statute, which does not contemplate that manufacturers must bear the burden of proof.[4]

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[3] Id.

[4] Social Security Act §1860D-14A(c)(1)(A)(vii).

III. Examples of Bases for Appeals

CMS provides several examples of reasons that manufacturers may seek an appeal, along with guidance on the types of evidence CMS expects manufacturers will submit when pursuing such appeals. We urge CMS first to make clear that the four reasons listed in the Draft Appeals Guidance are not the only reasons that a manufacturer may appeal the accuracy of an invoice. Such a clarification would be consistent with the multiple data field options the TPA has provided as reason codes for the dispute, which contemplate that an invoice may be disputed for a range of reasons; many of these reasons may also be legitimate reasons for appeal to an IRE.

We also urge CMS to clarify that a manufacturer may submit more than one reason for an initial dispute. While not indicated in the Draft Appeals Guidance, we understand from the webinars and associated materials provided by the TPA that a manufacturer may only be permitted to indicate a single reason for any specific dispute. We urge CMS to clarify that where there are multiple reasons for a dispute, a manufacturer may appropriately indicate all of the reasons for the dispute in the appropriate field. This is particularly important if CMS maintains its proposed policy that all information relevant to the appeal must be submitted at the time of the appeal and that no additional information may be submitted in subsequent rounds of the appeal.

With respect to the particular examples of reasons a manufacturer may dispute an invoice that CMS describes in the Draft Appeals Guidance, we provide the following comments:

A. Aberrant Quantity

CMS states that "[m]anufacturers who consider product dosages, whether more or less than three times the maximum FDA dosages, to be aberrant should be prepared to demonstrate to the satisfaction of the IRE that the dosage *represents a*

severe threat to the health of beneficiaries."[5] We note that the purpose of the appeals process is to ensure that Coverage Gap Discount Program payments are accurate. We believe that the standard that a manufacturer only engage in an appeal where it has a good faith reason to believe that an invoice is in error should be sufficient for the IRE to consider an appeal regarding a disputed invoice. It is quite possible that a quantity could be incorrect without the quantity representing a "severe threat" to the health of beneficiaries. This standard is not appropriate for a payment dispute. Whether a manufacturer was properly billed for a discount payment does not hinge on whether the quantity, even if accurately reflected on the invoices, would present a severe threat to beneficiary health. We urge CMS to re-consider this standard and instead adopt standards that more appropriately reflect the nature of the these disputes, which relate to payments that may result from inaccurate invoices.

B. Part B Drugs Ineligible for Discount

As CMS notes in the Draft Appeals Guidance, "many prescription drug products that are covered under Medicare Part B may also be covered under Medicare Part D depending upon the indication or provider setting."[6] CMS proposes in the Draft Appeals Guidance that a manufacturer may appeal to an IRE in these types of situations where "the manufacturer demonstrates that the applicable drug would not be covered under Part D because the Service Provider indicated on the detailed Manufacturer Data Report does not represent a pharmacy."[7]

We urge CMS not to use such a standard as a threshold for an appeal to an IRE. Manufacturers will not always have enough information to determine

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[5] Draft Appeals Guidance at 3 (emphasis added).

[6] Id.

[7] Id.

whether a drug is properly dispensed under Part B or Part D based upon the service provider. Drugs typically are covered under Part B versus Part D based on the manner dispensed and prescribed to a particular patient. While in many cases a therapy dispensed in a retail pharmacy is appropriately paid for under Part D, this is not always the case. For example, in some cases a retail pharmacy may dispense a therapy that usually is covered under Part B as part of durable medical equipment but may be covered under Part D in other circumstances.

The information provided to manufacturers as part of the Coverage Gap Discount Program would not allow a manufacturer to determine whether a drug was dispensed to a patient under Part B rather than Part D. While we expect that the majority of such circumstances would be resolved as the TPA reviews a disputed invoice, a manufacturer should be able to appeal a TPA determination if it is not satisfied that the TPA has provided sufficient response to support its determination that Part D coverage was appropriate. Indeed, in some cases, as contemplated by the Draft Appeals Guidance, a manufacturer will not even have the benefit of a TPA determination before having to file an appeal in order to meet the required timeframes. Where a manufacturer identifies a disproportionate number of Part D claims for a drug that most commonly is covered under Part B, the only way for a manufacturer to verify the accuracy of the coverage gap discount invoices is to dispute such an invoice and, where appropriate, to appeal an IRE determination, as is provided for by the statute.

IV. Implementation of the Draft Appeals Guidance

BIO encourages CMS to delay finalizing the appeals guidance until at least sixty days after the first quarter of invoices have been issued. This will allow manufacturers to view the first batch of invoices and better understand the types of outliers that may be appearing. This would better inform the kinds of issues that may arise in the dispute and appeals processes. Alternatively, we urge CMS to provide another opportunity for comment on the appeals process after the first year of the program. This will allow CMS to incorporate feedback from stakeholders

based on the program's initial experience and to update the appeals process in a manner that will be more efficient for all parties.

We also ask that CMS consider an extended timeframe for disputing invoices for the first few quarters. Given that this is a new program, this would provide manufacturers with the time necessary to adequately review and understand the data being provided with the initial invoices, while at the same time issuing the first few rounds of payments. An extended timeframe for the first few quarters is likely to reduce the number of disputes, as manufacturers will have the opportunity to fully review and understand the information provided.

Conclusion

BIO appreciates the opportunity to comment on the draft guidance on the Draft Appeals Guidance. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact Laurel Todd at (202) 962-9200 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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