BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

September 23, 2008

BY ELECTRONIC DELIVERY

Captain William Blanche
TRICARE Management Activity
Federal Docket Management System Office
1160 Defense Pentagon
Washington, DC 20301-1160

Re: Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals [DoD-2008-HA-0029; 0720-AB22]

Dear Captain Blanche:

The Biotechnology Industry Organization ("BIO") appreciates this opportunity to comment on the Department of Defense's ("DoD") proposed rule to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008 ("NDAA")[1] through a system of voluntary agreements for retail rebates based on utilization of covered drugs through the TRICARE Retail Pharmacy Program ("TRRx") ("Proposed Rule").[2] BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,150 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products.

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we closely monitor changes that impact the availability of pharmaceutical and biological products through the TRICARE Pharmacy Benefits Program, and have taken steps to work with DoD to find mutually beneficial solutions. In April, BIO submitted a letter to the TRICARE Management Activity ("TMA") that raised concerns regarding the Dear Manufacturer Letter that TMA issued on February 1, 2008 announcing its interim implementation of Section 703. We appreciate TMA's response to our letter. Moreover, BIO would like to express its appreciation to DoD for its efforts in compiling the Proposed Rule. DoD's implementation of its retail program through voluntary agreements is appropriate and clearly reflects substantial consideration and effort on the part of the agency. In general, the comments below are intended to raise issues pertaining to implementation and operation of the program. It is our hope that DoD will take these comments into consideration in crafting a refined and improved final rule. It is with this important goal in mind that our comments:

[1] Pub. L. No. 110-181, § 703.
[2] 73 Fed. Reg. 43,394 (July 25, 2008).

- Urge DoD to seek rebates from manufacturers on a prospective basis only, with effective dates tied to each individual rebate agreement, because a retroactive requirement is contrary to law and presents serious practical problems.
- Ask DoD to address the significant potential operational complications posed by the Proposed Rule.
- Urge DoD to make clear in its final rule that each manufacturer will have the discretion to opt to sign a voluntary agreement on a drug-by-drug basis.
- Request DoD to remove the Proposed Rule's broad penalty provisions as they are inconsistent with the rule's voluntary structure.
- Urge DoD to work with industry to craft rebate procedures and voluntary agreement terms that facilitate an evenhanded, cooperative relationship between the agency and manufacturers, including the drafting of clauses that ensure a fair and effective disputes process, fair resolution procedures for data discrepancies, and limit the available claims of the Federal Government.
- Request that DoD consider the impact of the Proposed Rule on other agencies and programs and seek input from those agencies and entities whose guidance is necessary to ensure an efficient and functioning rebate program.

These issues are discussed in depth below.

I. THE REBATE OBLIGATION SHOULD BE PROSPECTIVE

While the Proposed Rule does not announce a set proposed effective date for the commencement of the rebate obligation for manufacturers that enter into voluntary agreements, DoD has stated publicly that it intends to seek rebates from manufacturers retroactive to the date of enactment of the NDAA, January 28, 2008. As explained below, the voluntary agreements contemplated by the Proposed Rule must apply only in a forward-looking manner. Legal, policy, and practical operational considerations that counsel against retroactivity would preclude a requirement to pay rebates based on retail utilization that precedes the effective date of a final rule or a signed voluntary agreement. In view of these critical considerations, BIO strongly believes that the only viable approach is for DoD to adopt an effective date for the retail rebate requirement that is tied to the date of execution of a voluntary rebate agreement between DoD and a manufacturer.

A. Voluntary Agreements Should Apply Prospectively

It only makes sense that a manufacturer's obligation to pay rebates based on TRRx utilization should begin upon the execution of a voluntary agreement to pay rebates. For the program to be truly voluntary, a manufacturer cannot be forced to assume obligations predating the date on which a manufacturer voluntarily opts into the rebate regime. And, because the legal and practical reality is that Section 703's pricing provisions can be implemented only though a contract, DoD should not attempt to require a manufacturer that is interested in executing an agreement to accept a term mandating payment for utilization occurring prior to the manufacturer's voluntary assumption of that obligation—whether that be January 28, 2008, or the effective date of a final rule. Moreover, a retroactive requirement would unfairly require a

manufacturer to pay for utilization that it did not expect and for which it did not receive the benefit (or possibility) of UF placement that it would enjoy on a prospective basis.

Undoubtedly, DoD is free to attempt to negotiate a retroactive start date in a given agreement with a manufacturer; however, participation in the program should not require its acceptance—*i.e.*, a manufacturer not willing or able to pay rebates retrospectively should not be excluded from the rebate program. BIO feels strongly that prospective application tied to the date of a signed agreement should be the standard approach for all participating manufacturers and thus urges DoD to adopt such a provision in the final rule.

B. Retroactivity Is Disfavored in the Law

Regulations may be retroactive only when explicitly permitted by Congress.[3] As *Bowen* explains, "retroactivity is not favored in the law . . . . [A] statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms."[4] Section 703 states that it will be effective on the date of enactment of the statute; however it clearly does not provide that manufacturers shall be required to pay rebates retroactively on prior quarters' utilization—in fact, it does not speak of rebates at all. That any program implementing the statute cannot be retroactive is underscored by the fact that the statute further provides that implementation of its requirements requires the fulfillment of an additional condition: DoD must issue regulations implementing the program in order for it to move forward.[5]

Accordingly, DoD does not have a legal basis to reach back to the date of enactment of the NDAA.[6] If DoD were to proceed along these lines, it could jeopardize implementation of the program as a court could well hold that such an effort violates *Bowen*'s bright-line rule that an agency has no authority to promulgate regulations with retroactive effect absent an express grant of Congressional authority. To avoid this pitfall, we encourage DoD to craft its voluntary agreements under the Section 703 program as requiring prospective rebate payments only.

C. Retroactivity Presents Significant Operational and Practical Challenges

Because the contemplated rebates are tied to and may well impact Federal price calculations—including the Non-Federal Average Manufacturer Price ("Non-FAMP") and the Federal Ceiling Price ("FCP")—a retroactive date presents significant complications to those

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[3] *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) (holding that the Medicare Act did not allow for retroactive cost-limit rules).

[4] *Id.*

[5] Analogous Federal pricing regulations also warn against retroactivity. For example, the guidance issued by the Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") pertaining to discounts and rebates that has been issued pursuant to the Federal Anti-Kickback Statute. 42 U.S.C. § 1320a-7b(b). Under HHS OIG rules, to be protected under the discount "safe harbor" provisions of 42 C.F.R. § 1001.952(h), the terms of a rebate must be fixed in writing at the time of sale of a product; *accordingly, standard industry practice dictates that rebate agreements be structured to avoid the payment of rebates on prior sales*.

[6] The language of Section 703 regarding the applicability of its provisions to prescriptions filled "on or after the date of enactment," Pub. L. No. 110-181, § 703, is insufficient to constitute an explicit statement of retroactivity, especially given that the provisions can be implemented only though a contract. *See* above.

calculations. As discussed in greater depth below, the Department of Veterans Affairs ("VA") has yet to provide guidance to industry as to the proper treatment of rebates for purposes of Non-FAMP and FCP calculations, *e.g.*, whether TRRx utilization or rebates paid to DoD should be excluded from Non-FAMP as Federal sales and dollars. Depending on those decisions, the VA could well require manufacturers to revisit, recalculate, and restate the Non-FAMPs and FCPs for all covered drugs subject to a voluntary agreement with DoD. Such a scenario would present both industry and the Federal Government with tremendous complications and additional workload, especially in light of the length of time typically associated with promulgating a final rule as well as with restating VHCA calculations. Simply put, it would create a situation where all participating manufacturers would have to restate all of their FCPs for years during which retroactive rebates apply (*e.g.*, 2008 and any other subsequent years prior to the execution of a rebate agreement). To the extent that any restated FCPs would be lower than those originally reported, manufacturers would be faced with having to assess impact and overpayments to the Government based on FSS sales. The need to recalculate multiple quarters or years of calculations—depending on when a drug class is reviewed and agreements are executed—would create a situation that would be unworkable for the VA, industry, and DoD.

As with the VA calculations, there are uncertainties regarding how the Centers for Medicare and Medicaid Services ("CMS") will require companies to treat TRRx utilization and rebates in its calculations—including Best Price ("BP"), Average Manufacturer Price ("AMP"), and Average Sales Price ("ASP"). Here, too, it is quite possible that companies will have to go back to earlier quarters and adjust their treatment of the TRICARE retail utilization. Naturally, such adjustments also could impact State beneficiaries, for example, by requiring a manufacturer to supplement or seek a refund from the States of its Medicaid rebate payments depending upon the effect caused by the change in treatment of TRRx utilization. Accordingly, retroactive application of the program could have negative repercussions with respect to the CMS calculations, as well.

II. THE FINAL RULE SHOULD CLEARLY PROVIDE THAT MANUFACTURERS WILL BE PERMITTED TO CONSIDER VOLUNTARY AGREEMENTS ON A DRUG-BY-DRUG BASIS

BIO understands the Proposed Rule to allow each manufacturer to make decisions as to whether to sign voluntary agreements on a drug-by-drug (NDC-11-by-NDC-11) basis. Permitting participation on an individual drug basis will preserve the voluntary nature of the agreements. We therefore ask that DoD insert language in the Proposed Rule to reinforce that this drug-by drug approach to participation in the voluntary program is, in fact, DoD's intended approach.

III. THE PROPOSED RULE POSES SIGNIFICANT OPERATIONAL ISSUES

There are several operational issues raised in the Proposed Rule that DoD must clarify or resolve in the final rule.

A. Preauthorization and Remedies for Non-Participation

The Proposed Rule states that covered drugs not under a written agreement for retail rebates will be subject to a preauthorization requirement for access through TRRx. In addition, the language states that the "preauthorization requirement does not apply to other points of service under the Pharmacy Benefits Program"[7] such as at Military Treatment Facilities ("MTFs") or through the TRICARE Mail Order Pharmacy ("TMOP"). BIO believes that those drugs not subject to an agreement shall be available in these two points of service (MTFs and TMOP) as they have been available in the normal course prior to the issuance of the Proposed Rule.

The remedies section of the Proposed Rule, however, potentially is inconsistent with this language and BIO therefore requests that DoD clarify that section of the Proposed Rule. Proposed paragraph (q)(4) states: "In the case of the failure of a manufacturer of a covered drug to *make* or honor an agreement under paragraph (q), the Director, TMA, in addition to other actions referred to in this paragraph (q), *may take any other action authorized by law*."[8] This language is neither necessary nor appropriate. DoD and manufacturers presumably may take actions authorized by law vis-à-vis each other for failure to honor the terms set forth in executed voluntary agreements. More importantly, however, with respect to those manufacturers that do not enter into a voluntary agreement, the language violates the spirit of the Proposed Rule as a program premised on *voluntary* agreements. For the Section 703 framework to remain truly voluntary, DoD may not take adverse action against a manufacturer other than to require preauthorization for a drug of the manufacturer in the retail sector in cases where a voluntary agreement is not offered/executed. BIO urges DoD to remove the language in paragraph (q)(4) of the Proposed Rule relating to recourse against a manufacturer for failing to enter into an agreement as well as the final clause of this paragraph authorizing "any other action authorized by law."

B. Overpayment Recovery Provisions

Proposed paragraph (q)(3)(iii) states that "[a] refund due under this paragraph (q) is subject to [the overpayments recovery provisions of 32 C.F.R.] § 199.11."[9] BIO requests that DoD clarify the applicability of these provisions to the proposed rebate framework. We seek clarity regarding how the disputes, appeals, and offsets procedures of § 199.11 would apply and function in connection with the procedures ultimately contained in a final rule or later process and procedures guidance. Specifically, BIO seeks clarification as to whether DoD intends to treat unpaid rebates in the same manner as "erroneous payments" by DoD subject to the recoupment, demand, collection, referral, and other procedures contained in § 199.11. BIO strongly feels that any disputes regarding payment of rebates should be subject to a disputes process in line with the suggestions below, which fairly take into consideration the interests of both DoD and rebate-paying manufacturers.

[7] 73 Fed. Reg. at 43,397.
[8] *Id.* (Emphasis added).
[9] *Id.*

C. UF Placement Issues

The Proposed Rule states that a written agreement providing for at least FCP-based rebates is a "condition . . . of inclusion on the uniform formulary."[10] This provision begs two questions for which BIO requests clarification. First, is a manufacturer's agreement to provide FCP-based rebates an offer contingent on achieving formulary placement, *i.e.*, must a manufacturer whose product is not designated as UF still provide rebates? We believe that a manufacturer should not, and is not, bound to provide rebates offered in contemplation of receiving preferential UF placement for its product when such placement is not received.

Second is a drug that is not subject to a written rebate agreement precluded entirely from receiving UF placement? We believe that the Proposed Rule intends to allow such products to receive a UF designation in certain circumstances and through certain procedures, *e.g.*, through the exceptions process discussed below. We agree that products not subject to an agreement should be eligible for UF placement in order to ensure that DoD has flexibility to make certain that TRICARE beneficiaries have access to important, life-saving, or inexpensive products not subject to an agreement. We therefore urge DoD to clarify its intentions on this critical issue.

D. Exceptions process

BIO welcomes the proposed exceptions process contained in paragraph (q)(2)(E) of the Proposed Rule. This is one way in which DoD has shown its intention to allow non-participating products to achieve UF placement by providing for an exceptions process that allows the Director of TMA to exclude a particular drug from the definition of "covered drug" and thereby allow it to be placed on the UF where DoD, in its medical judgment, deems such an approach necessary. We support the creation of a robust exceptions process. Such a process will serve as an important mechanism by which DoD will be able to ensure that TRICARE beneficiaries can have access to important, innovative, and life-saving drugs that are produced by manufacturers that are not compelled to participate, as well as widely-utilized, low-cost products that present a cost-savings over competing products even in the absence of agreeing to provide FCP-based rebates.

With this in mind, BIO urges DoD to expand upon this provision by creating a clear and transparent process that allows manufacturers to know the procedures by which an exception may be sought and the standards by which it will be judged and ultimately may be granted. Such an open framework—with clear guidance, an opportunity for a hearing, and an appeals process—will provide a fair and reasonable way in which to have confidence that manufacturers are on an equal basis in their efforts to ensure that TRICARE beneficiaries have access to products that may, for legitimate reasons, not be offered under voluntary agreements.

[10] *Id.* The UF is an established set of covered prescription medications available to eligible TRICARE pharmacy beneficiaries mandated by the Pharmacy Benefits statute and regulations. *See* 10 U.S.C. § 1074g(2)(A); 32 C.F.R. § 199.21(a)(2).

E. Previously reviewed classes and drugs

We seek clarification regarding the treatment of products within previously competed therapeutic classes that are currently subject to UF Voluntary Agreements for Retail Rebates ("VARRs"). Noticeably, the Proposed Rule does not specify how DoD intends to treat such drugs that are subject to agreements providing for rebates calculated as a percentage discount off of Wholesale Acquisition Cost ("WAC"). For the sake of fairness and consistency, BIO urges DoD to adopt a uniform approach to handling these preexisting classes and agreements.

F. Rebate Processes and Procedures

The Proposed Rule does not articulate the processes and procedures applicable to the proposed rebate requirement. BIO urges DoD to create and circulate for review by industry a new set of rebate procedures detailing, for example, the handling and standardization of utilization data. In the interim, it is our assumption that the DoD intends to use the existing *Processes and Procedures Guide – Voluntary Agreements for Retail Rebates* (Apr. 1, 2008). DoD should clarify if it intends to do so, and for how long such interim procedures will be in effect.

IV. DOD SHOULD WORK WITH INDUSTRY TO CREATE A FAIR AND EFFECTIVE VOLUNTARY AGREEMENT

The Proposed Rule establishes a voluntary agreement framework to implement the requirements of Section 703. However, the Proposed Rule does not address the substance or terms of such agreements. BIO requests that DoD work with industry to craft an effective template agreement in order to ensure evenhanded and cooperative participation between the parties. An important part of this process will be for DoD to publicize a draft agreement prior to the issuance of the final rule in order to allow industry to provide its input regarding an agreement to which manufacturers will be parties. Bringing manufacturers into the process by providing notice and an opportunity to be heard regarding the voluntary agreements will, simply put, result in a more successful program.

Further, is quite possible that DoD will use the VARR template agreements framework as the basis for constructing its new voluntary agreements. In this regard, BIO requests that DoD consider the following important issues that must be addressed in its Section 703 voluntary agreements:.

A. Bad data issues

Through the VARR framework, DoD stated publicly that it would not scrub or exclude data that arguably should not be included in the TRRx data provided to manufacturers upon which rebate calculations would be based. For example, at the May 1, 2008, forum with industry, TMA officials stated that sales to 340B-eligible pharmacies, some of which also participate in the TRRx network, would not be excluded in the provided utilization data because DoD systems limitations could not identify which sales to those pharmacies represented actual 340B-eligible sales. Instead, DoD stated that a manufacturer would be required to scrub and examine the DoD-

provided data in order to determine which sales should be excluded from total utilization and seek such an exclusion from DoD. Such a system which places the burden on the manufacturer to eliminate potential improper double-dipping by a government entity is wholly inappropriate. BIO strongly requests DoD either to eliminate 340B sales data from TRRx utilization entirely or, at minimum, resolve data issues involving 340B-eligible sales to TRRx participating pharmacies before providing data to a manufacturer.

B. Disputes process issues

The Proposed Rule does not provide a clear process for dispute resolution. And, to the extent that DoD expects to draw from the existing VARR template agreement, the disputes process set forth in that agreement is inadequate. In the final rule DoD must create a full and fair mechanism for the resolution of disputes, which should be set forth in the text of the regulation and carried forward into the agreements between manufacturers and DoD. The current VARRs, for example, require a manufacturer to remit rebate payments based on DoD data with which the manufacturer disagrees regardless of the legitimacy of the dispute.[11] A manufacturer that does not timely pay on disputed amounts is subject to the draconian penalties of "termination of [its] UF VARR and reconsideration by the DoD [Pharmacy & Therapeutics] P&T Committee of the listed pharmaceutical agents' placement on the UF, in addition to any other remedies available to DoD."[12]

Going forward, BIO asks that DoD allow manufacturers to offset rebate payments by an amount for which it has a legitimate dispute regarding discrepancies between the data provided by DoD and that maintained by the manufacturer. Requiring a manufacturer to pay amounts in dispute prior to a resolution is patently unfair and places a tremendous burden on that manufacturer to seek recovery of such disputed amounts at a later date. We urge DoD to craft a robust, transparent, and evenhanded disputes process that allows for the offsetting or withholding of disputed amounts.

Such a process could well borrow from the Medicaid Drug Rebate Program dispute procedures. In that system, manufacturers may withhold disputed amounts. The Medicaid Drug Rebate Agreement provides that where a manufacturer in good faith believes that utilization data is erroneous, it is to provide written notice of the discrepancy and "shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date."[13] In the Medicaid program, a state is entitled to receive payment of undisputed amounts and, if a dispute is resolved in its favor, the disputed amount plus interest.[14] Similarly, DoD should (1) permit manufacturers to withhold disputed amounts during the dispute resolution process; and (2) be entitled to payment with interest in the event that DoD prevails in the dispute. Even though the current VARRs entitle a prevailing manufacturer to a return of its payments plus accrued interest, these procedures unfairly require a manufacturer to bear the risk of DoD's potential errors and therefore should not be included in the new voluntary agreement.

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[11] Voluntary Agreements for TRICARE Retail Pharmacy Refunds (VARR) for Uniform Formulary Placement or Utilization (versions 3.0 & 3.1) ¶ ¶ 8a-9a.
[12] *Id.*
[13] Medicaid Drug Rebate Agreement § V(b).
[14] *Id.*

C. Limitation of Government claims

Finally, a final rule—and the Section 703 implementing agreement—must contain some limitation on DoD's ability to assert claims for rebates based on past utilization. Data limitations and fairness necessitate that the ability to reach back must be cut off at some logical point. BIO believes that a logical end point for liability would be three years following the date of the utilization underlying the Government's claim. Under such a rule, DoD would be provided the flexibility to seek redress for rebates that have not been paid while at the same time not saddling a manufacturer with onerous recordkeeping requirements or presenting it with an unfair claim many years removed from the asserted utilization.

V. DOD MUST CONSIDER THE IMPACT ON RELATED FEDERAL PRICING PROGRAMS

The Proposed Rule raises several issues as to how Section 703 utilization should be treated under other Federal pricing programs. BIO urges DoD to reach out to its colleagues at the VA and CMS for input and clarification on this issue so that industry can appreciate the full impact of participation in this voluntary program.

First, as mentioned above, the VA has not issued guidance to industry regarding the proper treatment of TRRx sales and rebates for purposes of the Non-FAMP and FCP calculations following the enactment of Section 703. Specifically, industry needs guidance as to whether TRRx utilization and/or rebates should be excluded from the Non-FAMP calculation as Federal transactions. If recent history is a guide, the issue is far from clear. Under the predecessor TRRx program (implemented under the 2004 VA Dear Manufacturer Letter), rebates paid premised on TRRx's being a "virtual depot" were at first required to be excluded as Federal and later required to be included as commercial following that program's invalidation. VA guidance requiring exclusion appeared to be premised on the assumption that the program was required of all VHCA Master Agreement holders. After invalidation of the initial program, the VA made clear that companies offering voluntary rebate payments were not supposed to exclude as Federal sales the TRICARE retail utilization from their Non-FAMP calculations. Ultimately, the VA may well have to make a determination as to how "voluntary" the final rule's rebate obligations are.

Second, there are questions surrounding which Non-FAMPs and FCPs must be used as the basis for the rebate calculation (Non-FAMP minus FCP). The Proposed Rule states that the calculation shall use the "most recent annual non-Federal Average manufacturing prices," but that language leaves unclear whether a manufacturer should use the annual Non-FAMP and FCP in effect at the time of utilization or the annual Non-FAMP and FCP in effect at the time of the rebate calculation. Additionally, questions remain as to which Non-FAMP must be used for Q4 retail utilization: the annual Non-FAMP in effect for that year or the new annual Non-FAMP calculated following Q3 and submitted to the VA on November 15, the most recently submitted annual Non-FAMP.

Also, VA guidance is needed to aid manufacturers in dealing with anomalous Non-FAMP and FCP calculations. For example, rules need to be established regarding the proper treatment of negative, zero value, and false positive Non-FAMPs and FCPs or $.01 FCPs in order to avoid unreasonable or absurd rebate calculations. The bottom line is that the VA and industry input is critical to resolve these types of questions.

Finally, like the VA, CMS has not yet weighed in on the treatment of Section 703 utilization for purposes of its price calculations—including BP, ASP, and AMP. Companies need to have this information in assessing the full impact of participation in the Section 703 program and in order to ensure compliance with requirements under these three pricing programs.

V. CONCLUSION

BIO greatly appreciates the opportunity to comment on the important issues raised by the Proposed Rule, and we look forward to working with DoD to ensure that TRICARE beneficiaries continue to have access to critical drug and biological therapies. As discussed above, however, there are significant issues and potential complications that must be resolved in order to ensure an equitable and functional rebate program. A vigorous give and take with industry is the hallmark of the rulemaking process and as such we urge DoD to consider our concerns in order to assist it in crafting an effective final rule. We welcome the opportunity for an in-person meeting to work with you to assist in the processes of finalizing the Proposed Rule. Please feel free to contact Laurel Todd at (202) 962-9220 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Sandra Dennis
Deputy General Counsel for Health

/s/

Laurel Todd
Director of Reimbursement
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cc: Melbourne A. Noel, Jr., Office of General Counsel, Department of Veterans Affairs
Kerry N. Weems, Acting Administrator, Centers for Medicare and Medicaid Services