October 30, 2000

Mr. Gary J. Krump  
Deputy Assistant Secretary  
Department of Veterans Affairs  
810 Vermont Avenue, N.W.  
Washington, D.C. 22204

Re: Draft Amended Master Agreement under the Veterans Health Care Act of 1992

Dear Mr. Krump:

On behalf of the Section of Public Contract Law of the American Bar Association ("the Section"), including its Health Care Contracting Committee, I am submitting comments on the above referenced matter. The Public Contract Law Section consists of attorneys and associated professionals in private practice, industry and Government service. The Section’s governing Council and substantive committees contain a balance of members representing these three segments, to ensure that all points of view are considered. In this manner, the Section seeks to improve the process of public contracting for needed supplies, services and public works.

The Section is authorized to submit these comments under special authority granted by the Association’s Board of Governors. The views expressed herein have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, therefore, should not be construed as representing policy of the American Bar Association.

I. Introduction

The Section appreciates the opportunity to comment on a draft Amended Master Agreement and encourages the Department of Veteran Affairs ("VA") to continue the practice of seeking input from the various stakeholders in connection with the implementation of the Veterans Health Care Act of 1992 ("VHCA"), 38 U.S.C. § 8126. The Section looks forward to providing a similar forum for the VA to obtain comments and analysis of future health care related procurement issues.

The Section’s comments on the proposed Amended Master Agreement focus on potential legal issues and areas of the agreement that could benefit from additional clarity. The Section recognizes that many stakeholders under the VHCA may start or conclude with different legal conclusions and interpretations than those discussed herein. Such differences can be expected in a large, industry-wide program. The Section’s comments are provided to highlight issues for further discussion by all stakeholders. Should the VA and the manufacturers be unable to agree on proposed
changes to the Master Agreement, the Section recommends that the disputed change be deleted to maintain the status quo and allow the issue to be resolved, if necessary, through the Master Agreement’s disputes mechanism or otherwise. The Section’s comments on the draft Amended Master Agreement are provided below.

II. The Section’s Comments on the Department of Veteran Affairs Draft Amended Master Agreement

A. The VA Should Consider Establishing a Regulatory Rather Than a Contractual Scheme to Implement Changes in Policies and Procedures Under the VHCA

The VHCA set up a regime premised on a voluntary agreement where, in order to receive reimbursements under Medicaid and other programs, a manufacturer must enter into a pharmaceutical pricing agreement (“PPA”) with the Secretary of the VA. 38 U.S.C. § 8126(a). The VA implemented the PPA by incorporating, among other things, the terms of the Master Agreement into the PPA. The Master Agreement provides that,

Except for changes in the notification address as specified in paragraph VII(A) above, this Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by the way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

AMA at ¶ VII.E.[1]

The above provision appears to limit the VA’s power to unilaterally modify the Amended Master Agreement to incorporate VA’s past or future policy interpretations not contained within the four corners of the Master Agreement or the PPA, including the interpretations set forth in the VA’s past “Dear Manufacturer Letters.” The Master Agreement further provides that it “shall be construed in accordance with the Federal common law . . .” AMA at ¶ VII.D. Under Federal common law, the Government is bound to the terms of an agreement it signs by an authorized party, including a requirement, such as set forth above, that all modifications be only bilateral in nature and in writing. See *Len Company and Associates v. United States*, 385 F.2d 438, 445 (Ct. Cl. 1967) (contracting officer’s unilateral change to Navy housing contract was not cognizable under the terms of a contract that required the signature of all parties to any contract change; the contract expressly limited the contracting officer’s authority was expressly limited to proposing changes).

On that note, the Master Agreement does not include any type of “Changes” clause such as in the Federal Acquisition Regulation that grants the Government the right to unilaterally change the contract within certain limits. See *e.g.*, 48 C.F.R. § 52.243-1. Given the current VHCA scheme, the Section encourages all stakeholders under the VHCA to find common ground upon which a bilateral amendment to the Master Agreement can be executed. The VA’s request for comments on a draft Amended Master Agreement is a positive step toward such an objective. As a practical matter, however, the goal of bilaterally amending each Master Agreement in a uniform manner may not be achievable given the number of such agreements and the potentially conflicting positions of the parties.

Alternatively, the VA could consider transitioning to a regulatory scheme where the PPA and Master Agreement incorporate by reference regulations promulgated to implement the VHCA. For example, the Medicare and Medicaid programs require providers to sign a “participation agreement” under which they agree to follow the rules and regulations of those programs. Social Security Act, Pub. L. No. 89-97, §§ 89-97, 8866a(1) (Medicare); 1902(a)(27) (Medicaid). Although a regulatory scheme has its own disadvantages (*e.g.*, the period it takes to implement a proposed rulemaking), the advantages include uniformity and a full and open public process to effectuate proposed changes. In addition, a rulemaking process can, in many cases, provide sufficient time for manufacturers to modify their commercial business practices and contracts in response to a proposed change, and remove the uncertainty regarding the binding nature of the unilaterally imposed Dear Manufacturer Letters.

Further, by issuing the Dear Manufacturer Letters, the VA may have already crossed into the regulatory area. An agency pronouncement of policy that alters an existing regulatory scheme, affects parties’ rights, and does not merely remind the affected parties of existing duties, is subject to rulemaking procedures, including notice and
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comment under the APA. Jerris Ceramic Arts, Inc. v. Consumer Product Safety Commission, 874 F.2d 205 (4th Cir. 1989), National Treasure Employees Union v. Reagan, 685 F. Supp. 1346 (E.D. La. 1988) and Trinity Indus., Inc. v. Dole, 760 F. Supp. 1194 (N.D. Texas 1991). Many of the Dear Manufacturer Letters could be interpreted as substantive changes affecting manufacturers’ rights. For example, changes involving the inclusion or exclusion of sales from the calculation of the non-FAMP (such as nominal prices and sales to federally funded clinics and hospitals the enclosures of PHS sales) are arguably substantive pronouncements of policy that affect the manufacturers’ rights. The changing definitions alter prices, affect profitability of government sales, and impact how manufacturers will negotiate commercial contracts in the future. Such governmental action often requires a rulemaking, even if the action changes an agency’s prior interpretive rule rather than a legislative rule. See Alaska Professional Hunters Assn., Inc. v. Federal Aviation Admin., 177 F.3d 1030, 1033-34 (D.C.Cir. 1999).

In sum, the Section recommends that the VA review the current system of maintaining the potentially less flexible contract-based scheme for implementing changes in VHCA policy. Such a scheme requires 100 percent participation by all stakeholders in bilateral contract modifications to maintain uniformity among manufacturers. In contrast, implementing changes through a rulemaking provides an open process, adequate public notice, and uniformity.

B. The VA Should Clarify When a Manufacturer May Elect to be a Dual or Single Pricer

Paragraph B.4 of the Amended Master Agreement was not in the original Master Agreement. It states that “The manufacturer must elect whether it will be a dual pricer or a single pricer as defined above.” This provision does not identify when a manufacturer must elect whether it will be a dual or single pricer. Nor does it state whether a manufacturer may change its election and, if so, when it may effect such a change. The election form attached to the draft agreement states that the election will be effective immediately upon award of a contract and will remain in effect throughout the term of the Federal Supply Schedule (“FSS”) contract. Nevertheless, neither Paragraph B.4 nor the form is clear as to whether the election may be subsequently changed. The VA’s written advice to industry entitled “Interactions Of Price Reductions Clause With Federal Ceiling Prices (FCPs)”, May 1, 1997, states:

In the event that you choose to elect dual pricing during a future FCP annual reporting month (November), negotiations shall be reopened to establish separate FSS prices for non-VA/DOD/PHS/IHS/Coast Guard authorized FSS users (OGAs).

This advice suggests the VA will permit annual elections. Because the manufacturer must submit a new FCP every year, such a policy appears reasonable. Moreover, there may be circumstances in which a manufacturer should be able to change its status as a dual or single pricer, for example, if it has merged with another manufacturer, or if the VA opens up the schedule to new users. The Section recommends that Paragraph B.4 of the Amended Master Agreement be clarified as to when a manufacturer may elect or change a prior election to be a single or dual pricer.

C. The VA Should Clarify the Amended Master Agreement Regarding the FCP for Non-Commercial, Government-Specific Packaging

The proposed text at the end of paragraph II.F of the Amended Master Agreement provides, "[F]or those covered drug NDCs [i.e, National Drug Code (“NDC”)] not sold commercially, the [Federal Ceiling Price (“FCP”)] shall be based on the nearest commercially available package size of the product." This provision could be more clearly drafted and is susceptible to numerous interpretations, some of which are arguably inconsistent with the VHCA.

Typically, as discussed elsewhere in the Master Agreement, the FCP is determined based on commercial sales of an NDC offered on the FSS. This new provision is geared to address situations where companies obtain separate NDCs for VA-specific packages and provides that the FCP will be "based on the nearest commercially available package size of the product." Nevertheless, the provision does not clearly enumerate the intended meaning of the term "based on" for purposes of determining the FCPs for FSS-specific NDCs. It appears that the term "based on" could be interpreted to mean that the FCP for the nearest commercially-available package size simply would be adopted for the FSS-specific product. If the package were larger and more expensive, then FCP would be artificially inflated. If the
package were smaller and less expensive, then the FCP would be artificially low. Such interpretation could result in unnecessarily high or low FCPs that bear no relationship to a fair and reasonable commercial price of a covered drug.

Another interpretation of the term "based on" might require the VA to look to the unit price of the nearest commercially available package size of the product and multiply this by the number of units in the FSS-specific package. Therefore, if the VA-specific package were a bottle of 100 tablets, and the closest commercial package were a bottle of 50 tablets (half the size of the VA package), the VA would look to the price of the a single tablet in the bottle of 50 and then multiply this times 100 to determine the FCP for the VA-specific bottle of 100. Although this method would appear to be more reasonable than the direct application of FCPs for the nearest commercially available package size, it also could produce unreasonable results.

Often, based on economies of scale, the larger the package size of a product, the lower the price will be for each unit of a drug. So, in the above example, if the FSS package had 100 tablets, and the nearest commercial size were 50 tablets, it could result in a unit commercial price of the drug considerably higher than the unit price of the 100-pack would be if such package were offered commercially. Inclusion of such unreasonably high unit price of the drug would necessarily cause the FCP of the FSS-specific 100-pack of the drug to be unnecessarily high.

One could also envision the opposite being the case. This might occur if the FSS-specific package were significantly smaller than the nearest size of commercially available product. If the VA required special, unit-of-use packaging, and the next smallest size were, for example, a 50-tablet package, the commercial price of such product were based on the price of a single unit within the commercial 50-tablet package, the price would likely be far less than the commercial price of a unit-of-use package offered on the commercial market would be. In such case, the FCP offered to the VA (based on the 50-pack) likely would be significantly lower than the FCP would have been if there had been commercial sales of the FSS-specific package.

Given the ambiguous nature of the current proposed language and the potential difficulties with the various manners of basing non-Federal Average Manufacturing Price (“non-FAMP”) on other products' commercial sales, the Section would propose that the applicable language include the inserted bolded text as follows:

"For those covered drug NDCs not sold commercially, the FCP generally shall be computed using the per unit value for [based on] the nearest commercially available package size of the product and multiplying this figure by the number of units in the FSS-specific package. Where the difference in package sizes is substantial (25% or greater), the parties shall agree to an adjustment of the FCP to ensure a reasonable and appropriate price is established."

This language would provide that the FCP for the FSS-specific packaging generally would be extrapolated based on per-unit pricing of the nearest commercial package size. Nevertheless, the language would provide for flexibility in cases where use of such extrapolated number would not be reasonable or appropriate because there was a significant size disparity between the FSS-specific package and the nearest commercial package.

D. The VA Should Revise the Amended Master Agreement Regarding the Treatment of Custom/Private Label Packaging

The Section recommends that the VA clarify the text added in paragraph II.B.8 of the Amended Master Agreement concerning the VA's treatment of custom/private label packages of covered drugs. The new language provides:

Custom or Private label packages of covered drugs that have contents which are exactly identical to the contents of commercial packages sold in the general market place and on the FSS carry different NDCs merely to reflect FDA's acceptance of and tracking of a package labeling variation. A manufacturer does not need to offer to the FSS a bona fide "custom" or "private" label package size of a covered drug that is not commercially available in the market place or to national accounts similar to VA. However, if the bona fide custom package has contents identical to a commercially available package that is sold through
wholesalers with a different NDC number, then the custom package's wholesale sales must be included with the commercial package's wholesale sales in calculating the non-FAMP for the commercial product. If the identical custom package is sold only direct—not through a wholesaler—then all of the direct sales must be included with the commercial package's wholesale sales to calculate the latter's non-FAMP.

AMA at ¶ II.B.8 (emphasis added).

Under this provision, the VA would permit a company to not offer on the FSS a custom package of a covered drug that is prepared specifically for one particular commercial customer. If this exclusion were utilized by a manufacturer, however, the manufacturer would be required to include all sales of such custom packages in the non-FAMP of "the commercial package" of a product the manufacturer offers on the FSS with "contents identical" to those of the custom package. This non-FAMP requirement could be construed to require double counting of certain products in a manner inconsistent with the basic terms of the VHCA and the Master Agreement. Moreover, the term "contents identical" is not defined. As discussed below, the Section recommends that the VA clarify its treatment of custom/private label packaging prior to inclusion of this paragraph in the Amended Master Agreement.

1. The Provision May Permit Impermissible Double Counting of Commercial Transactions in a Manufacturer's Non-FAMP Calculations.

The Amended Master Agreement would require a manufacturer of a custom package of a covered drug with "contents identical to a commercially available package that is sold . . . with a different NDC number" to include the custom package's commercial sales in calculating the non-FAMP for the commercial product. This provision undoubtedly is geared to cover situations where a manufacturer holds several NDCs for a product that all are under the manufacturer's own NDC labeler code in different package variations, one of which is a "custom" commercial package that it sells only to one customer group (e.g., one nursing home group purchasing organization). Under the proposed language, such custom product would not be offered on the FSS, but its commercial sales would be required to be included in the computation of non-FAMP for the package of the product with "contents identical" that is offered on the FSS. This requirement is unobjectionable. Nevertheless, given that the provision requires a manufacturer to include in its non-FAMP calculation all sales of custom packaged covered drugs "with a different NDC number" from FSS products, it also could be interpreted as requiring a manufacturer to factor in sales of a product that it does not market commercially, but rather supplies to another manufacturer that ultimately markets the product under a separate NDC owned by that other manufacturer. As described below, such a requirement would result in double counting of such commercial sales in non-FAMP, which would be inconsistent with the terms of the VHCA and the current Master Agreement.

In addition to selling its covered drug under its own NDC labeler code, a manufacturer (e.g., "manufacturer A") may also supply a pharmaceutical to another pharmaceutical company (e.g., "manufacturer B"). The package of this transferred covered drug would have contents chemically identical to those of a package of the drug offered generally on the commercial market by manufacturer A – e.g., the same product dosage, form, strength, and package size. Manufacturer B may apply for and obtain a separate NDC under its own labeler code for the drug and sell it commercially as part of its own product line.

The proposed language in the Amended Master Agreement could be construed to require manufacturer A to include commercial sales of manufacturer B's drug in the non-FAMP calculation for its FSS product with "contents identical." Such requirement would not only be difficult for manufacturer A to meet because it would not have access to the commercial sales data for manufacturer B's NDCs, it would also result in double counting of commercial sales of the transferred custom package in calculation of non-FAMP for those covered drugs that are marketed to the FSS by separate companies under separate NDCs.

This potential for double counting stems from the definition of "manufacturer" under the Master Agreement, which provides that a manufacturer is "the entity holding legal title to or possession of the NDC number for the covered drug." See Master Agreement at ¶ 1.G. Thus, when a pharmaceutical manufacturer (e.g., manufacturer A

produces a covered drug and retains legal title to the NDCs for such covered drug under its NDC "labeler
code," the manufacturer is required to list all NDCs of that drug on its FSS contract and on its VHCA Pharmaceutical
Pricing Agreement (PPA). When a separate company (e.g., manufacturer B above) obtains an NDC for a covered drug
that is already covered under another company's labeler code, it is considered the "manufacturer" for this new NDC,
and is required (1) to offer the NDC on its own separate FSS contract (2) to enter into its own Master Agreement and
PPA, and (3) to report non-FAMPs and FCPs. The original manufacturer that produces and supplies the covered drug
to manufacturer B is not required to offer manufacturer B's NDCs on its FSS contract – or to calculate non-FAMPs or
FCPs for these NDCs – because it does not own legal title to them.

Nevertheless, the proposed language regarding "custom" packages in the Amended Master Agreement could
require manufacturer A to take into account the commercial sales of covered drug under manufacturer B's NDC labeler
code when it calculates non-FAMP for its own NDCs of this covered drug on the FSS. As is evident, such requirement
would result in double counting of commercial sales of this custom package in both manufacturer A and manufacturer
B's non-FAMP calculations. Moreover, it could require Manufacturer A to report commercial sales of products under
manufacturer B's NDC labeler code – when products under this labeler code are not required to be included on
manufacturer A's Master Agreement or PPA in the first place.

To avoid this inconsistency with the basic terms of the Master Agreement and double counting of commercial
sales of certain custom packages offered commercially, the committee would recommend adding the following bolded
language (and deleting the bracketed text) in the third sentence of paragraph II.B.8:

"However, if a manufacturer's bona fide custom package has contents identical to a commercially available package that is sold through wholesalers with a different NDC number that incorporates that manufacturer's labeler code, then the custom package's wholesale sales must be included with the manufacturer's commercial package's wholesale sales in calculating the non-FAMP for the commercial product."

This revision would ensure that only custom products under a manufacturer's own labeler code would be required to be included in non-FAMP calculations for covered drugs on a manufacturer's FSS contract.

2. The "Contents Identical" Requirement is Ambiguous.

Apart from its concerns regarding the potential for inclusion of commercial sales of NDCs that are not owned
by a manufacturer, the Committee also notes that Amended Master Agreement paragraph II.B.8 may be susceptible to
collision, and potentially, unreasonable interpretation, because the non-FAMP inclusion requirement applies only
where the custom package has "contents identical" to a product package offered on the FSS. It would appear that the
term "contents identical" certainly is intended to apply in circumstances where the custom package is in the same form,
dosage, and strength, as well as package size as the product available on the FSS. Thus, when packages identical in all
of these aspects to an FSS item are offered as part of a custom package deal, sales of such custom packages would be
included in the non-FAMP. Nevertheless, the text of paragraph II.B.8 leaves open the possibility that the non-FAMP
inclusion requirement would apply to packages that are identical in terms of form, dosage and strength to FSS items,
but that are provided in different package sizes.

Under the terms of the Master Agreement, non-FAMPs and FCPs are computed separately for each different
package size of a covered drug (i.e., each NDC). If a "custom package" of a covered drug (with a separate NDC) were
provided that was in the same package size, as an NDC offered on a manufacturer's FSS contract, there would be no
question as to how to utilize commercial sales of the custom package in computation of non-FAMP of an FSS product.
These sales would be factored directly into non-FAMP. Nevertheless, application of the rule would be far less clear if
the "contents identical" requirement were interpreted only to require that the form, dosage, and strength of a custom
product – and not package size – be identical to a package available on the FSS. If the rule were so interpreted, the
same questions would arise as in the context of calculating FCP for an FSS-specific package size (see discussion
above in Section D.1). If this were the case, it would be necessary to clarify which packages of product these
commercial sales would be linked with – for example, it logically would appear to be the nearest size of product
available on the FSS. In addition, as in the context of FSS-specific custom packages, it would be necessary to set forth
a specific methodology for determining the price of such sales to be inserted into the non-FAMP calculation for products on the FSS.

The Section recommends that the VA clarify Amended Master Agreement paragraph II.B.8 to indicate that the term "contents identical" requires that the form, strength, dosage, and package size of the custom product be identical to the commercially available product. Clarification to this effect would simply require adding these requirements in parenthesis after the first use of the term "contents identical" in the text. In other words, the first two sentences of the paragraph should be revised to as follows to include the inserted bolded text:

Custom or Private label packages of covered drugs that have contents which are exactly identical (i.e., identical in form, dosage, strength, and package size) to the contents of commercial packages sold in the general market place and on the FSS carry different NDCs merely to reflect FDA's acceptance of and tracking of a package labeling variation. A manufacturer does not need to offer to the FSS such a bona fide "custom" or "private" label package size of a covered drug that is not commercially available in the market place or to national accounts similar to VA . . .

Nevertheless, if the VA were to opt to interpret the term more broadly, the Section would suggest inserting the following text at the end of Amended Master Agreement paragraph II.B.8:

"The price of commercial sales of custom-labeled covered drugs in package sizes that differ from those package sizes currently available on the FSS generally shall be included with the commercial sales of the nearest size of such product available on the FSS for purposes of determining non-FAMP. The price of each commercial sale of "custom product" included in non-FAMP shall be computed using the per unit value for the product and multiplying this figure by the number of units in the FSS package. Where the difference in package sizes is substantial (25% or greater), the parties shall agree to an adjustment of the FCP to ensure a reasonable and appropriate price is established."

This added text would provide for a reasonable and predictable approach to inclusion in non-FAMP of sales of custom packages of product in sizes that differ from those available of the FSS.

E. The VA Should Revise the Amended Master Agreement Regarding its Treatment of New Covered Drugs

The Amended Master Agreement incorporates the past practice of calculating a “Temporary FCP” by taking .76 of the non-FAMP based on the first thirty days of sales. AMA at ¶ H.1 The past practice, however, allowed some flexibility for manufacturers that are unable to capture the relevant chargeback data within the first thirty days of sales. For some manufacturers, it may take longer than thirty days to capture the data needed to calculate a Temporary FCP. The VA should consider adding language to Paragraph H.1 that preserves the past flexibility regarding the period after which a manufacturer can reasonably determine a Temporary FCP based upon initial sales data. For example, the proposed language could be revised to state that “[t]he temporary FCP is determined by taking .76 of the non-FAMP based on the 1st 30 days of sales or another period as agreed to by the manufacturer and the Secretary” (new language in italics).

The Amended Master Agreement also does not address the price at which a manufacturer may sell a covered drug within the first thirty days of launching sales of the drug. The Veterans Health Care Act requires a manufacturer to make each covered drug, including newly launched drugs, available on the Federal Supply Schedule as a condition to receiving payment for the purchase of drugs or biologicals from State Medicaid and certain other programs. 38 U.S.C. § 8126(a)(4). The Section recommends that the VA add language that allows a manufacturer to sell a new covered drug under the Federal Supply Schedules for the first thirty days after launch (or such other period as mutually agreed) at .76 of the drug’s list or catalog price after subtracting any standard trade discounts (i.e., prompt payment discount). After thirty days of sales (or such other period as mutually agreed), the manufacturer can submit a new
“Temporary FCP” and proceed as set forth in the Amended Master Agreement.

The VA should also consider adding language clarifying that there is no retroactive adjustment (up or down) to a “Temporary FCP” once a “final FCP” is submitted pursuant to the terms of the Amended Master Agreement. As currently drafted, the Amended Master Agreement is silent on this issue. The Section understands that VA’s past practice did not require a retroactive adjustment. If one of the purposes of amending the Master Agreement is to incorporate past practices, the Section recommends including language in Amended Master Agreement Paragraph H.1 to address the absence of a retroactive adjustment to any “Temporary FCP.”

F. The VA Should Clarify A Manufacturer’s Obligations Regarding the Submission of Quarterly Reports

The Amended Master Agreement provides that the quarterly non-FAMP reports need only be submitted “upon the request of the Secretary or his designee . . .” AMA at ¶ D.2. Although this new provision appears to be intended to lessen the burden on manufacturers, it is unclear whether the Secretary’s request for a quarterly report would be prospective or retrospective in nature. For example, under the current draft language it is unclear whether the Secretary or his designee (e.g., the VA Inspector General during an audit) can request the preparation and submission of “old” quarterly reports that were not previously requested prior to their due date. If so, the manufacturer’s reduced burden can become illusory. We recommend the addition of language clarifying that there is no requirement for a manufacturer to generate a quarterly report not requested by the Secretary or his designee prior to its due date.

The existing Master Agreement requires Manufacturers to “retain all records relevant to the generation of the above [quarterly and annual] reports and calculations of annual Federal price ceilings for not less than five years from the date of their creation.” AMA at ¶ D. Therefore, the data used to calculate annual FCPs (which necessarily includes the data that would have been used to generate quarterly submissions) would remain available for the five-year period. Without the clarification suggested above, a request by the VA to subsequently generate and submit quarterly reports dating back, for example, four years earlier, would trigger a new requirement to keep the data used in the creation of those reports for another five years. Depending on the date of the request for the generation and submission of a quarterly report, a manufacturer could potentially be required to retain data for up to ten years. If the VA does not intend to impose such a potential burden, the Section recommends that it adopt the clarification outlined above.

G. The VA Should Consider Revising Certain Definitions in the Amended Master Agreement or Leave Them Unchanged to Preserve the Legal Options of the Parties

1. Non-Federal Average Manufacturer Price.

The term “Non-Federal Average Manufacturer Price” is defined in the original Master Agreement as having the meaning “set forth in Section 8126(h)(5)” (as established by Section 603 of the VHCA). The statutory definition provides that the non-FAMP calculation is based on:

- prices paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account – (A) any prices paid by the Federal Government, or (B) any prices found by the Secretary to be merely nominal in amount.

38 U.S.C. § 8126(h)(5). The VA’s definition in the Amended Master Agreement modifies that definition with the following language:

and shall exclude; (i) sales to the wholesaler for which the manufacturer processes a chargeback based on a sale to the Government; and (ii) purchases (and associated chargebacks) by PHS “covered entities” (grantees, disproportionate share hospitals, etc.) if the prices for those transactions were determined by PHS pursuant to Section 602 of the Veterans Health Care Act of 1992.
AMA at ¶ 1.J. In other words, the VA’s interpretation of Non-FAMP only excludes sales through wholesalers to Government entities and federally-funded entities, if the prices are at (and not below) ceiling prices required by Section 602. This position is restated by the addition of the following new language in Paragraph B.7 of the Amended Master Agreement regarding what prices shall be included in the Non-FAMP calculation:

Purchases (and associated chargebacks) by PHS grantees or disproportionate share hospitals at less than the price determined by PHS pursuant to Section 602 of the Veterans Health Care Act of 1002 shall be included.

The VA’s interpretation of Non-FAMP arguably creates a disincentive for manufacturers to grant voluntary reductions to federally funded entities below the statutory ceiling. The VHCA sought to accomplish two fundamental goals: to cap prices to certain Government agencies (Section 603) and certain “covered” federally-funded entities (Section 602), and to reverse the effect of the Omnibus Budget Reconciliation Act of 1990 (“OBRA 90”), Pub. L. No. 101-508, 104 Stat. 1388 (1990), on the VA and federally-funded clinics and hospitals. OBRA 90 required manufacturers to calculate Medicaid rebates based on “best price.” Because these agencies and entities were not exempt from “best price,” they began to experience substantial price increases.

As the legislative history makes clear, in addition to establishing price ceilings on purchases by Government agencies, and exempting Government sales from “best price,” the legislation provided “protection from drug price increases to specified Federally-funded clinics and public hospitals.” H. Rept. 102-384, Part 2, 102d Cong. 2d Sess. at 12. The House Committee Report explains

Like the prices charged to the VA, prices charged to these “covered entities” would be exempt from the calculation of the Medicaid “best price” for purposes of determining the Medicaid rebate. The Committee expects that this exemption will remove any disincentive that the Medicaid rebate program creates to discourage manufacturers from providing substantial voluntary or negotiated discounts to these clinics, programs, and hospitals. (emphasis added.)

Id. In addition, Congress imposed on manufacturers price reductions to these entities “at least as great as those which Medicaid receives.” Id. The report again explains:

In giving these “covered entities” access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible...

Id.

The report further states that a covered entity is not precluded “from negotiating greater price reductions,” and “is not limited to purchasing drugs with its Federal grant funds.” Id. at 15-16. Thus, the legislative history reflects Congressional intent to treat Government entities and “covered entities” the same in order to secure the best prices where federal funds are involved. Accordingly, sales to federal agencies and Section 602 entities, regardless of price, should be excluded from the calculations of best price, and chargebacks associated with sales to federal agencies and Section 602 entities should be treated the same for purposes of calculating both non-FAMP and the Average Manufacturer Price (“AMP”) under Medicaid.

Moreover, it should be noted that the exemption from the Non-FAMP calculation for prices charged Government agencies still applies if they are below the Section 603 ceiling. These sales are exempt because the Federal Government pays for them. The same is true of sales to clinics and hospitals receiving federal funds. Because the statute exempts prices paid by the Government, rather than purchased by the Government, it should be construed as exempting from the non-FAMP calculation chargebacks for sales to Government agencies and covered entities regardless of price.

In sum, the Section recommends that the VA reexamine its definition of Non-Federal Average Manufacturer Price and exclude prices below the Section 603 ceiling. In the alternative, the Section recommends that VA delete the
refers to PHS covered entities in Subparagraph (ii) of the definition and allow the issue to be resolved, if necessary, through the Agreement’s disputes mechanism or otherwise.


The Section recommends that the VA reexamine its definition of “nominal” as outlined above or, in the alternative, delete the proposed modification to that definition and allow the issue to be resolved, if necessary, through the Agreement’s disputes mechanism or otherwise. The term “Nominal Price” is defined in the original Master Agreement as “any price less than 10% of the non-FAMP in the previous quarter.” Master Agreement at ¶ K. As noted above, the statutory definition of non-FAMP excludes prices that the VA finds to be nominal in amount. 38 U.S.C. § 8126(h)(5). In the Amended Master Agreement, the VA modifies the definition by adding the following language:

from a sale (usually below cost) designed to benefit the public by financially aiding disadvantaged, not-for-profit covered drug dispensaries or researchers using a drug for an experimental or non-standard purpose.

AMA at ¶ K. This provision appears contrary to the legislative history which intended for “the exclusion of nominal prices from non-FAMP calculations [to be] consistent with section 1927(c)(1)(C) of the Social Security Act, which excludes prices which are nominal in amount from best price calculations.” 138 Cong. Rec. 517901 (Dec. 8, 1992). Congress noted that HCFA regulations define nominal price as a price that is 10% or less of Average Manufacturer Price (“AMP”); nevertheless, in the case of the VA, Congress wanted to leave the determination of the amount to the Secretary of the VA. 138 Cong. Rec. S17901 (Dec. 8, 1992)(emphasis added). Although the statute gives the Secretary discretion to determine what is nominal in amount, there is nothing in the statute or its legislative history to indicate that Congress intended to do anything other than exclude prices below the amount set by the VA.

The legislative history provides that:

The exclusion of nominal prices from calculation of the non-FAMP of a covered drug is intended to preclude a negative effect on industry pricing policies toward non-federal entities that rely on nominally-priced products.

138 Cong. Rec. S17901 (Dec. 8, 1992)(emphasis added). Thus, Congress did not intend to disturb existing industry pricing policies in connection with non-federal entities that rely on nominally priced products. Nominal prices have historically been granted to entities that do not fit within the VA’s narrow definition. For example, a manufacturer may grant nominal prices to hospitals in order to penetrate an established market and create more price competition. Following the VA’s logic, a nominal price to a disproportionate share hospital would be included in non-FAMP if the manufacturer’s reason for granting the low price was based on commercial considerations and not financial aid. Because inclusion of a nominal price in non-FAMP can drive down the VA’s price, the VA’s conditions create a disincentive to grant nominal pricing where such pricing policies are the norm. This result is particularly harmful to certain entities in light of the VA’s policy with respect to Section 602 prices discussed above.

As noted, under the Medicaid Rebate Program, on which Section 603 is modeled, the amount at which a drug price will be considered nominal is very similar (i.e., 10% of the prior quarter’s AMP). Nevertheless, HCFA does not impose any conditions on whether a price is nominal in addition to meeting the specified amount, or force manufacturers to determine whether the nominal price meets such conditions. Indeed, manufacturers have argued that it is so administratively difficult to differentiate eligible from ineligible prices below 10% of non-FAMP under the VA’s criteria that the majority cannot exclude any prices below the nominal amount as they are entitled to under the statute. As a result, industry pricing policies are negatively affected. This is precisely the result that the nominal price exclusion is intended to prevent.

III. Conclusion

The Section appreciates the opportunity to provide these comments and is available to provide additional information or assistance as you may require.
For purposes of brevity, the Amended Master Agreement will be referred to as the “AMA” in all citations herein, followed by a specific paragraph number (e.g., AMA at ¶ VII.E). In contrast, the term Amended Master Agreement will not be abbreviated in the text in any sentence discussing that Agreement. The existing Master Agreement shall be referred to herein as the “Master Agreement” without any abbreviation.

The "labeler code" represents the first five digits of the NDC. The second two segments are called the "product code" and the "package code." The product code is the four-digit middle segment of the NDC that represents dosage, form, and strength of the product. The two-digit package code denotes the package size of the product.

This sale from manufacturer A to manufacturer B would not be considered in non-FAMP because it would not be a commercial sale through a wholesaler.

Each package size of a "covered drug" is denoted with a different NDC and the distinguishing feature between a covered drug offered in varying product sizes is the third segment of the NDC. When custom products of the same package size as a regular commercial product are produced under a separate NDC, such custom products generally will have a separate product code – i.e., the second (four-digit) segment of the NDC.