TAB A - PROPOSED ADDITIONS TO VA PPV CONTRACT MODIFICATION BY IHS

The IHS would like to propose two additional provisions to the VA PPV contract modification. These concern IHS access to Tribal pharmaceutical purchase data and the funding mechanism for IHS-related VA PPV contract management functions.

ACCESS TO IHS AND TRIBAL PHARMACEUTICAL PURCHASE DATA

The IHS is requesting that the contract modification include a section stating that Tribes and/or their intermediaries agree to allow the VA PPV to release pharmaceutical purchase data to the IHS.

When VA negotiates a National Drug Contract (NDC), in most cases VA agrees to purchase a certain amount of the drug to get a reduced price. Additionally, for closed-class medications the VA agrees to use one drug in preference to all others in a particular class. The IHS and Tribes agree to these conditions when participating in these contracts. When new contracts are being considered, the IHS must provide the VA with IHS and Tribal drug usage data. These data come from AmerisourceBergen reports currently provided to the IHS. The IHS needs to continue to receive these usage reports to be able to provide the VA with the required data.

Additionally, the VA PPV purchase data allows the IHS to examine usage practices. One of the roles of the National Pharmacy and Therapeutics Committee will be to review these data to see where pharmaceutical costs can be reduced. One example involves using simvastatin instead of atorvastatin in the treatment of hyperlipidemia. Using simvastatin has the potential to save $1.2 million per year nationwide.

The VA PPV data is also used to determine increases in IHS and Tribal pharmaceutical costs. This information is used by the IHS in the annual budget formulation process to justify the need for additional pharmaceutical funds from Congress.

FUNDING VA PPV CONTRACT MANAGEMENT

The IHS is requesting that IHS, Tribes and Tribal intermediaries be assessed a 3/10 of one percent (0.3%) contract management fee to allow the IHS to conduct contract management activities related to the VA PPV contract. This equates to a $3,000 management fee for every $1 million of medications an IHS or Tribal site purchases through the VA PPV contract. Funds would be assessed by the VA PPV when medications are purchased. This fee would apply to facilities purchasing directly or using an IHS intermediary.

The VA is responsible for managing the national VA PPV contract with AmerisourceBergen. The VA uses a contract management fee, charged to all other Government accounts (non-VA users), to conduct contract management activities ranging from contract development and negotiations to formulary management to research and development of NDCs.

In a similar fashion, the IHS needs to charge a fee to carry out Agency and Tribal administrative functions related to the VA PPV contract. Such management is vital to ensure medications can be purchased at greatly reduced costs. Using VA PPV and NDCs saves IHS and Tribes more than 50 percent on drug costs annually. Currently, contract management activities are funded by distribution charges to facilities using IHS intermediaries to process medication orders. As Tribes begin to order directly from the PPV, these funds will not be collected. Since management of the VA PPC contract is not an IHS residual function, funds must be available to ensure contract activities are maintained.

The VA and AmerisourceBergen have requested a single point of contact for the IHS and Tribes. This means that while each Tribe ordering medications directly from the VA PPV will be required to have a separate contract with AmerisourceBergen, the VA and AmerisourceBergen want to have one contact for the IHS and the Tribes for general administrative matters related to the contract. This is very important since the VA PPV contract management fee for other Government accounts was negotiated based on this single point of contact.

The IHS and Tribal sites receive many benefits from IHS contract management activities. A few of these activities include:

- Working with the VA to ensure the IHS and Tribes are included in the PPV contract solicitation. The VA PPV contract is solicited every 5 years; approximately 12 to 18 months before each solicitation, IHS staff begin meeting with the VA to ensure the IHS and Tribes are included and our issues are addressed.

- Providing professional advice and assistance to the VA on questions and matters related to IHS and Tribal pharmaceutical usage and requirements during contract solicitation, selection, award, and administration periods.

- Working with the VA National Acquisition Center to ensure IHS and Tribes are included on all NDCs. This requires providing to the VA purchase history information and commitment documents for each ordering facility. Currently, approximately 400 NDCs require yearly review. This very time consuming process is essential to ensure IHS and Tribal sites continue to receive the best possible price for medications.

- Identifying and reporting overcharges on drug prices and ensuring that if IHS and Tribal customers have been overcharged, they receive rebates or credits from manufacturers or the VA PPV. For example, when McKesson was the PPV, the company had computer problems. The IHS identified millions of dollars in overcharges and recovered those overcharges.

- Resolving problems related to errors, billing, medication availability, delivery, and other issues. The IHS conducts regular conference calls with site staff and VA representatives to discuss PPV issues, concerns, and problems.

- Facilitating the pooling of accounts for Tribal facilities that do not meet the $60,000 annual minimum for VA PPV purchases so that they also have access to the VA PPV.

- Ensuring that up-to-date IHS and Tribal Drug Enforcement Administration certificates required to legally purchase medications are kept on file with the VA and the VA PPV.

- Ensuring that medication ordering programs (e.g., Echo and iEcho) are operating correctly and that facilities are satisfied with VA PPV customer service.

- Responding to questions from IHS site staff and Tribes related to NDCs, prices, terms, substitution, pricing discrepancies, lock-out or override procedures, etc.

- Working with the IHS National Pharmacy and Therapeutics Committee to relay to VA which pharmaceuticals IHS and the Tribes would like considered for NDCs.

- Reviewing drug contract solicitations to ensure that bioequivalence and therapeutic classifications meet IHS and Tribal needs.

- Researching, gathering, consolidating, and providings pharmaceutical purchase history information (including information for Tribal facilities) to IHS Headquarters, National Core Formulary Committee, and other groups as appropriate.

- Verifying Tribal eligibility with VA and drug manufacturers when questions arise.

NATIONAL CORE FORMULARY AND NATIONAL PHARMACY AND THERAPEUTICS COMMITTEE

Standard of Care Issues:

One of the new IHS functions related to managing the VA PPV contract is the implementation of a National Core Formulary (NCF) and a National Pharmacy and Therapeutics Committee (NPTC).

The IHS NCF is not a comprehensive drug formulary. Its purpose is to specify a core set of drugs that must be made available (required for IHS sites and highly recommended for Tribes) to IHS beneficiaries in order to maintain appropriate standards of care for common medical conditions. The first edition of the NCF includes approximately 50 drug entities used to treat six high-prevalence, high-risk, and high-cost disease categories. The NCF is not designed to replace local formularies but to ensure that local formularies have, at a minimum, essential medications available to treat specific conditions.

While almost all sites currently have the NCF drugs on their local formularies, some sites have eliminated standard-of-care drugs from their local formularies. In most cases, this was done solely as a strategy for managing costs.

Patient Access:

A second benefit to the NCF is to make the drug benefit “portable” for patients. Whether a person travels or simply cannot always get to the same facility due to transportation issues, an NCF will increase the likelihood of that person, if on a typical medical regimen, being able to get his/her regular medication and not having to switch drugs.

The NCF also assists health care providers whether they are local providers, consultants, or contract health services (CHS) providers. Since these NCF medications will be available at all sites, providers will know that a patient who is treated at one facility and transferred to another will be able to get the prescribed medication at the receiving facility.

Patient Safety:

An NCF can play an important role in improving patient safety. If all facilities have the same core medications, a patient transferring from one care location to another will not have to switch medications, obviating the need for additional monitoring and follow-up often necessitated by such changes.

Additionally, an NCF encourages providers to use a relatively

small set of drugs for most prescriptions, leading to increased familiarity with these medications on the part of the provider and pharmacist. Also, the consistent use of disease-state management guidelines will promote appropriate drugs use and reduce the likelihood of errors.

Cost Shifting:

Drug costs are increasing at a rate several times that of the core rate of inflation. As some sites eliminate needed drugs from their formulary, patients move to other facilities to continue to receive their medications. With an NCF, all facilities would have the essential medications, and patients would be less likely to move from site-to-site solely to acquire medications.

Cost Savings:

While the NCF's main purpose is improving patient outcomes, cost savings are also possible. As sites implement the NCF and use these medications in preference to non-NCF drugs, sites should see reductions in overall medication costs. This is because NCF medications tend to be on NDCs, and while just as effective as other drugs, they are much less expensive.

Not all sites will see a cost savings. The few sites that have eliminated some NCF medications from their local formulary due to cost considerations will need to make these medications available to their patients. While this may pose a financial hardship at first, it is hoped that overall costs can be reduced at these sites by NPTC medication usage reviews.

National Pharmacy and Therapeutics Committee:

The NPTC is essential to the contract management process and the NCF. The NPTC will be responsible for:

- Updating the NCF

  Clinical practice standards are constantly changing as new information on disease states and medications become available. For the NCF to be a useful tool for IHS and Tribal providers, it must be regularly reviewed and updated by the NPTC to include the latest information and clinical protocols.

- Serving as a resource to local P&T committees

  The NPTC members, in addition to working on the NCF, will serve as expert resources to clinical staff working on local formularies or who want to do drug utilization reviews or other types of pharmaceutical-related evaluations.

- Recommending Clinical Care Protocols

  The NPTC will develop clinical care protocols or refer providers to nationally recognized protocols for various disease states. While use of these clinical care protocols will be voluntary, it is well recognized that use of good clinical protocols can improve patient outcomes and may reduce overall costs.

- Reviewing Data for Potential Cost Savings

  As mentioned previously, one of the major functions of the NPTC will be to examine the use of medications by the IHS and Tribes. The NPTC will look for ways to improve clinical outcomes and reduce or avoid costs. Facilities will be informed of actions they can take, such as changing from one drug to another in a particular class, which can substantially reduce their overall drug costs.

PPV Contract Management Costs:

Because the PPV contract management fee is a percentage tied to the amount of drugs purchased through the PPV, costs are roughly proportional to the size of the facility and the population served, and directly proportional to the facility's drug expenditures.

The overall budget for contract management is approximately $480,000 per year. This is 0.3 percent of the approximately $160 million per year that the IHS and Tribes spend on pharmaceuticals. Funding pays for staff costs, travel expenses, Web site development, maintenance, and printing costs.

<u>Staffing</u>

1 full-time Pharmacist for contract management
1 full-time Support Staff for contract management
1 half-time Physician Chairperson for the NPTC
1 full-time Pharmacist Vice-Chair for the NPTC
12 non-paid field IHS and Tribal Physicians and Pharmacists NPTC members (only travel costs are paid for these positions).

<u>Travel</u>

- The NPTC will hold at least two face-to-face meetings annually with conference calls at least quarterly.
- Members will attend national and regional meetings to discuss issues and promote the use of the NCF.
- There will be travel to IHS and Tribal sites to work with local P&T Committees.
- There will be travel to VA and Department of Defense formulary committee meetings.

<u>Web Site</u>

An NCF and NPTC Web site will be developed and maintained.

<u>Summary</u>

Funding for IHS staff is essential to ensure the VA PPV contract continues to work for both the IHS and Tribes. While other funding mechanisms may work, the proposed contract management fee is a simple process that poses minimal costs to most facilities, especially when it is compared to the potential cost savings. Even modest changes in prescribing practices related to the NCF will more than pay for contract management costs.

Tab B – Background Information on Other VA PPV Contract Modifications

RESPONSES TO THE SEPTEMBER 18, 2002, DEAR TRIBAL LEADER LETTER

Thirteen Tribes responded expressing the following concerns with the proposed contract modification:

- Tribes want the choice either to order directly from the VA PPV or to use an IHS intermediary.
- They want to be treated “just like IHS” relative to pricing, distribution fees, and delivery schedules.
- They want the minimum order quantity to be reduced. The requirement to purchase $5,000 worth of medications per month would exclude many Tribes.
- They are concerned about hardware and software repair or replacement once the warranty period ends.
- They suggest that disputes be settled in Tribal or Federal court, not State courts.
- They want indemnification and insurance issues addressed as they relate to Federal Tort Claim Act coverage.
- They note the contract modification lacks detail in many areas.
- They are concerned that the VA PPV contractor can terminate the contract or refuse to ship medications without a stated appeals process.

PROPOSED ADDITIONS TO THE CONTRACT MODIFICATION PROPOSED BY VA OR VA PPV

The VA and AmerisourceBergen provided additional comments and suggestions to modify the VA PPV contract. These comments are noted below, and the most recent proposed modification is at the end of this document.

- Stipulate that payments to be received through Electronic Funds Transfer.
- Include a section on receipt of goods and reporting of shorted or damaged goods.
- Clarify that deliveries are made Monday through Friday and how this affects the 24- and 48- hour delivery periods.
- Add that handheld ordering devices will be available for a $25 per month rental fee.

- Regarding access to ordering mechanisms, the PPV will make a “reasonable best effort” to ensure an effective ordering method.

- Regarding customer qualifications, customers must meet commercially reasonable credit standards.

IHS COMMENTS TO VA ON THE PROPOSED ADDITIONS TO THE CONTRACT MODIFICATION

After reviewing the Tribal comments, IHS provided the VA with a number of suggested changes to the proposed modification to the PPV contract (see attached IHS letter to VA dated January 13, 2003).

Proposed Modification to the VA Pharmaceutical Prime Vendor Contract €

Below is the most recent version of the proposed VA PPV contract modification including changes (see underlined and "Deleted" sections) since than those seen in the September 18, 2002 Dear Tribal Leader Letter. These changes were suggested by VA and AmerisourceBergen and do not include changes related to the IHS Director's comments to VA from the January 13, 2003 letter.

The Contract between the VA and AmeriSource shall be modified as follows: €

The following terms shall apply to all tribal entities purchasing directly under that one certain contract between the Department of Veterans Affairs and AmeriSource Corporation assigned the contract number V797P99-PPV-0001 (the "VA Contract") through HHS. For purposes of this modification, each tribal entity or Indian Health Service ("IHS") facility which becomes controlled by a tribal entity is referred to as "Customer". Except as specifically set forth herein, all other terms and conditions of the contract remain unchanged.

1. PRICE OF GOODS: Price of Goods shall be the contract or non-contract cost of the product together with the distribution fee.

	Price of Goods on a Cost +/- basis			
Average Monthly Volume Per Delivery Location	Monthly Prepay Terms	Next Day Pay Terms	Weekly Pay Terms	Semi-Monthly Pay Terms
$5,000 - $15,000	0.80%	1.05%	1.25%	1.50%
$15,001 - $25,000	0.60%	0.85%	1.00%	1.20%
$25,001 - $50,000	0.00%	0.25%	0.40%	0.60%
$50,001 – and up	-0.25%	0.00%	0.15%	0.35%

However, to the extent a Customer has a more favorable Price of Goods schedule as of the original date of this Modification, such Customer's schedule shall be grandfathered into this Modification.

All payments must be received through Electronic Funds Transfer.

Deleted: payment schedules are based on

AmeriSource reserves the right to charge and collect interest on late payments as set forth in the VA Contract and to put the account on credit hold preventing shipment in the event of late payment.

Customer's payment terms shall be determined by mutual agreement between AmeriSource and each individual Customer.

Deleted: method

AmeriSource will generate credit memos within two business days of notice from customer to correct billings for shortages. Customer must notify AmeriSource within 24 hours of receipt of goods of any shortages. Damaged or short dated product must be returned to AmeriSource for credit, which will be processed for credit within two business days of receipt back to the distribution center. Credit memos will be available for application to invoices and do not have to be applied to the original transaction invoice. Invoices are not to be short-paid for shortages or damaged merchandise.

2. MINIMUM PURCHASES: Customer shall purchase a minimum of $5000 per calendar month as measured on a quarterly basis. In the event that Customer does not order a minimum of $5000 per month, AmeriSource reserves the right to refuse to ship and to terminate the agreement with the Customer pursuant to this Modification upon thirty (30) days written notice to Customer and the VA contract officer. There shall be no penalties for the first thirty (30) days after ordering.

Deleted: this Contract

3. **DELIVERIES**: Deliveries shall be scheduled as follows:

Deleted: ¶

Purchases per Month	Deliveries per Week
$5000 - $10,000	1 delivery per week
$10,001 - $25,000	2 deliveries per week
$25,001 - $50,000	3 deliveries per week
Above $50,000	5 deliveries per week

However, to the extent a Customer has a more favorable delivery schedule as of the original date of this Modification, such Customer's schedule shall be grandfathered into this Modification.

Delivery shall be within 24 hours of an order request where normal commercial delivery is available and within 48 hours in all other locations, in both cases for Customers with multiple deliveries per week. Delivery shall be provided Monday through Friday. Orders placed on Thursday with 48 hour delivery shall be delivered the following Monday, and Orders placed on Friday with 24 hour delivery shall be delivered the following Monday. Delivery schedules will be adjusted for legal holidays in a similar manner.

Deleted: week.¶

Customer agrees to inform AmeriSource of any anticipated material changes in ordering patterns.

4. **COST REPORTING:** Customer understands that rebates and discounts may need to be reported as a part of its cost for purposes of federal and/or state healthcare programs, including for purposes of 42 CFR 1001.952(h).

5. **PROPRIETARY SOFTWARE**: AmeriSource grants to Customer a non-exclusive non-transferable license the ("License") to use the AmeriSource's proprietary software (the "Software"), including without limitation the ECHO system and the iECHO software, solely for the purposes of this Modification at the Customer locations, in accordance with, and subject to, the terms and conditions of this Modification.

AmeriSource will provide the Software in the form of a CD-ROM, diskettes or other media containing machine-readable object-code. AmeriSource may provide the Software to Customer on more than one medium. Regardless of the type or size of the medium that Customer receives, Customer may only use the medium appropriate for its designated computer or network server.

AmeriSource or its suppliers retain all rights to the Software and related documentation (including, but not limited to any images, "applets," photographs, animations, video, audio, music and text incorporated therein, copyright, trade secrets and other proprietary rights) which are not expressly granted to Customer under this Modification. All updates, enhancements, modifications and additions to the software developed by AmeriSource or any other entity will be the sole and exclusive property of AmeriSource.

Customer agrees that it and its locations will not copy, duplicate, or prepare derivative works from any element of the Software except that (i) Customer may make one (1) back-up or archival copy of the Software at each Customer location as permitted by the copyright law of the United States; and/or (ii) install the Software on a single hard disk at each Customer location. Customer shall not remove any copyright or proprietary rights notice included in or on any Program element, and shall reproduce all such notices in or on all copies made by Customer.

6. **HARDWARE:** Certain hardware (the "Hardware") will be provided to each Customer location purchasing at least $50,000 per month at no charge for use with the Software only. Title to the Hardware shall remain in AmeriSource. Sites ordering below $50,000 may utilize InterNet ordering through the Software. Customer locations that have Hardware on site as of the effective date of this Modification shall be entitled to retain the Hardware under the same conditions under which the Hardware was originally received. For those accounts ordering below $50,000 per month, a handheld ordering device shall be available at a lease rate of $25 per month.

7. PROPRIETARY SOFTWARE/HARDWARE LIMITED WARRANTY: AmeriSource warrants that the Software, if operated as directed, will perform substantially in accordance with its documentation for a period of ninety (90) days from the effective date of this Modification as it applies to each Customer. AmeriSource also warrants that the Hardware provided by AmeriSource, and the diskettes, CD-ROMs, or other media on which the Software is provided, will be free from defects and workmanship under normal use for a period of ninety (90) days from the Effective Date. **Other than as set forth in this paragraph, (a) AmeriSource makes no warranty, express or implied, including without limitation, any implied warranty of merchantability or fitness for a particular purpose, and (b) no oral or written information provided by AmeriSource or its employees, agents or representatives will create any representation or warranty.**

AmeriSource's entire liability, and Customer's exclusive remedy, for breach of the warranties contained in this paragraph shall be, at AmeriSource's option, to (i) repair or replace the Software so that it performs substantially in accordance with its documentation; (ii) advise Customer how to achieve substantially the same functionality with the Software as described in any documentation through a procedure different from that set forth in any documentation, or (iii) replace defective media returned within ninety (90) days of the Effective Date. Any replacement software shall not serve to extend the original ninety (90) day warranty.

8. ACCESS TO ORDERING MECHANISMS: AmeriSource shall use its commercially reasonable best efforts to ensure that Customer has an effective method to order product.

9. COMPLIANCE WITH LAW: For purposes of this Modification, Customer agrees to act in accordance with all laws of the United States of America, including, without limitation, the Federal Food, Drug, and Cosmetic Act as amended by the Prescription Drug Marketing Act of 1987, all as amended. In the event that Customer commits one or more acts of diversion, Customer shall reimburse AmeriSource for all chargebacks made with regard to the diverted product(s) and for all costs and legal fees incurred by AmeriSouce with regard to the diversion, and AmeriSource reserves the right to terminate or remove any and all contract pricing at the direction of the manufacturer in connection with its FFS contract. The VA or its designee shall monitor ordering through reports provided under the Contract. AmeriSource agrees to cooperate with the monitoring efforts of the VA or its designee, and to notify the VA if AmeriSource identifies a suspicious ordering pattern.

Deleted: contracts

10. INDEMNIFICATION: Customer agrees to indemnify, defend and hold harmless AmeriSource, its subsidiaries and assigns from and against all claims, losses, damages, liabilities and expenses (including but not limited to attorneys' fees and court costs) arising as a result of negligence, illegality or wrongdoing of any kind alleged or actual on the part of Customer.

11. LIMITATION OF LIABILITY: In all cases, Amerisource Corporation's liability shall be limited to actual damages proven by the Customer. In no event shall Customer be entitled to indirect, consequential or punitive damages.

12. INSOLVENCY: In the event of any proceedings, voluntary or involuntary, in bankruptcy or insolvency by or against Customer, the inability of Customer to meet its debts as they become due, or in the event of the appointment, with or without Customer's consent, of an assignee for the benefit of creditors or of a receiver, then AmeriSource shall be entitled, at its sole option, to terminate this Contract and Modification as it applies to Customer without notice and to withhold shipment of any order without any liability whatsoever.

13. INSURANCE: Customer shall maintain professional liability insurance in the amounts of not less than one million dollars ($1,000,000.00) per incident and five million dollars ($5,000,000.00) in the aggregate. AmeriSource shall be named on Customer's policy as an additional insured.

14. CUSTOMER QUALIFICATIONS: Each Customer must meet AmeriSource's commercially reasonable credit standards before it shall be permitted to sign an agreement with AmeriSource pursuant to this Modification.

15. **ENTIRE AGREEMENT**: This Modification supersedes all prior agreements between the parties with regard to the subject matter hereof and there are no other understandings or agreements between them except the VA Contract. No representations, warranties, or promises pertaining to this Modification have been made by, or shall be binding on, any of the parties, except as expressly stated in this Modification. This Modification may not be changed orally, but only by an agreement signed by the party against whom enforcement of any such change is sought.

16. **SEVERABILITY:** If any provision or clause of this Modification conflicts with applicable law, such conflict shall not affect other provisions of the Modification or the VA Contract if the provisions can be given effect without the conflicting provision. To this end the provisions of this Modification are declared to be severable. If any provision of this Modification is held to be invalid or unenforceable for any reason whatsoever, including any conflict with applicable law, the remaining provisions shall remain valid and unimpaired, and shall continue in full force and effect.

17. **WAIVERS:** Failure of either party to enforce strict performance of any obligations under this Modification shall not constitute a waiver of such party's right to thereafter enforce every term and condition hereof.

18. **NOTICES**: All notices required to be given hereunder shall be made in writing and shall be deemed sufficiently given if delivered by certified or registered mail return receipt requested, overnight or same-day delivery (such as Federal Express or special courier), at the addresses set forth. The notice shall be effective on the date indicated on the return receipt in the case of certified or registered mail, effective on the date following the date of mailing in the case of overnight delivery and effective the date of delivery in the case of same-day delivery at the addresses below or at such addresses as may subsequently be provided in writing to the respective parties:

19. **GOVERNING LAW**: The construction, application and enforcement of the agreement between the Customer and AmeriSource pursuant to this Modification and the VA Contract shall be governed by the laws of the United States and the state surrounding the applicable Customer's tribal lands. Customer agrees to waive any rights it may have or may assert, to have any dispute or question regarding this Modification or the VA Contract resolved or heard by Tribal Council.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 13 2003

Indian Health Service
Rockville MD 20852

TO: Executive Director
National Acquisitions Center
Department of Veterans Affairs

FROM: Interim Director

SUBJECT: Comments on the Proposed Modification of the Department of Veterans Affairs' Pharmaceutical Prime Vendor Contract

Thank you for the opportunity to provide comments on the proposed modification to the Department of Veterans Affairs' (VA) Pharmaceutical Prime Vendor (PPV) contract between the VA and AmerisourceBergen. The proposed contract modification, when signed by the VA and AmerisourceBergen, changes the current VA'S PPV contract-setting terms and conditions under which Tribes can directly access services of the VA's PPV contract as they are now allowed to do under Section 450j(k) of the Indian Self-Determination and Education Assistance Act (ISDA), Public Law 93-638. Once the modification is approved and the Interagency Agreement between the VA and the Indian Health Service (IHS) is changed, each Tribe or Tribal organization opting to exercise the modification would sign a separate agreement with AmerisourceBergen.

The IHS has consulted with Tribes and Tribal organizations regarding the proposed contract modification, and I have attached the resulting comments. Please contact CAPT Robert E. Pittman, Principal Pharmacy Consultant, IHS, if you have questions or concerns regarding any of these comments. He can be reached on (301) 443-1190.

Charles W. Grim, DDS

Charles W. Grim, ~~D.D.S.~~, M.H.S.A
Assistant Surgeon General

Attachment

GENERAL COMMENTS

The Pharmaceutical Prime Vendor (PPV) contract modification should state that each Tribe or Tribal organization choosing to exercise this option must sign a separate contract with AmerisourceBergen. The contract would reference the terms and conditions set out in the contract modification as the basis for Tribal direct-access to the VA's PPV services. It should also clarify that (1) in carrying out an Indian Self-Determination and Education Assistance Act (ISDA), Public Law 93-638, agreement, a Tribe is deemed an executive agency and part of the IHS for purposes of eligibility for the VA discount program under section 603 of the Veterans Health Care Improvement Act; and (2) the Tribe does **not** enter into a direct relationship with AmerisourceBergen **as part of the Indian Health Service (IHS)**, thereby making the IHS liable for contract claims. The contract modification should clarify that it creates no contractual or other liability on the part of the IHS to AmerisourceBergen or the customer Tribe.

The contract modification should contain a termination provision allowing a Tribe to terminate the direct-access relationship with AmerisourceBergen. The option to access the VA's PPV through the IHS remains available to the Tribe if the Tribe decides to terminate its direct-access relationship.

SECTION 1 – PRICE OF GOODS

The contract should specifically state that the "Average Monthly Volumes" apply to each delivery location rather than to each entity, since a Tribe may have more than one facility site and may expect to be able to pool the purchase dollars from these sites to reduce the distribution fee (even though medications are being sent directly to several different locations).

The clause grandfathering in Tribes at a more favorable price should explicitly state that the Tribes that have been using an IHS intermediary will have the benefit of the IHS pricing and distribution fees. The clause should also detail the current IHS pricing, delivery-fees payment schedule, etc., into which these Tribes will be grandfathered.

The modification should reference the VA's PPV contract sections that pertain to credit for medications not shipped (shortages) or damaged goods, and to prepayment terms.

SECTION 2 – MINIMUM PURCHASES

The IHS requests the VA and AmerisourceBergen to review the $5,000 per month minimum order for possible ways to reduce this amount so that smaller facilities can participate in the VA's PPV contract.

There are concerns about the "refuse to ship" part in this section. As part of the 30-day written notification process informing a Tribe that the Agreement is being terminated, a statement should be added referring the Tribe to an intermediary that can place orders with the VA's PPV for the Tribe.

SECTION 3 – DELIVERIES

The modification needs to reference the VA's PPV contract or provide additional clarification about the delivery process for sites ordering less than $50,000 worth of medication per month. For example, if a site only has one delivery per week (orders between $5,000 and $15,000), will these orders be held until a certain day of the week, or can they be shipped immediately with future orders held for the following week?

The clause grandfathering in Tribes at a more favorable delivery schedule should explicitly state that the Tribes that have been using an IHS intermediary will have the benefit of the IHS delivery schedule. The clause should also detail the current IHS delivery schedule.

SECTION 4 – COST REPORTING

No changes requested.

SECTION 5 – PROPRIETARY SOFTWARE

No changes requested.

SECTION 6 – HARDWARE

Reference the section of the VA'S PPV contract that states the conditions under which the hardware is originally received.

SECTION 7 – PROPRIETARY SOFTWARE/HARDWARE LIMITED WARRANTY

Reference the VA's PPV contract sections that provide for fixing or replacing defective software or hardware beyond the warranty period. If there is a cost for replacement or for extending the warranty, it should be specified.

SECTION 8 – ACCESS TO ORDERING MECHANISMS

No changes requested.

SECTION 9 – COMPLIANCE WITH LAW

Add a reference to Section 105(k) of the Indian Self-Determination and Education Assistance Act, 25 United States Code (U.S.C.) 450j(k), in the first sentence.

If there are additional reasons for terminating a contract or situations under which the VA's PPV would refuse to ship medication orders, they should be detailed or referenced in the contract. Appropriate sections in the VA's PPV contract need to be referenced identifying the process to appeal contract termination or the removal of any contract pricing.

SECTION 10 – INDEMNIFICATION

Tribes and Tribal organizations are concerned about the indemnification clause in the proposed modification. Some Tribes believe this clause exposes them to potentially high costs without defining what these costs are or limiting a Tribe's potential liability. Several Tribes believe this issue is covered by the Federal Tort Claims Act (FTCA) when a Tribe is carrying out its ISDA Agreement. The IHS believes the FTCA would not cover these issues. This section needs additional discussion.

SECTION 11- LIMITATION OF LIABILITY

No changes requested.

SECTION 12 – INSOLVENCY

The Tribes need to be notified when the VA's PPV contractor is terminating the contract and withholding shipment of medications. Additionally, the Tribe needs to be referred to an IHS intermediary to ensure there is some means of acquiring the medication.

SECTION 13 – INSURANCE

By statute, Tribes and their employees carrying out contracts and compacts under the ISDA are deemed part of the Public Health Service for purposes of the FTCA, and the Federal Government would be substituted as the defendant with respect to claims cognizable under the FTCA. See implementing regulations at 25 C.F.R. Part 900, Subpart M. Section 13 requires professional liability insurance to protect AmerisourceBergen. While many Tribes contracting and compacting under the ISDA carry wraparound liability insurance that is supplemental to the FTCA coverage, we would like to discuss further whether Section 13 is necessary given the FTCA coverage.

SECTION 14 – CUSTOMER QUALIFICATIONS

No changes requested.

SECTION 15 – ENTIRE AGREEMENT

The only change requested is that "explanations" referenced in the original VA's PPV contract apply to this contract (e.g., if a definition of "Diversion" is referenced, it also applies to the modification).

SECTION 16 – SEVERABILITY

No changes requested.

SECTION 17 – WAIVERS

No changes requested.

SECTION 18 – NOTICES

No changes requested.

SECTION 19 – GOVERNING LAW

While many Tribes expressed willingness to have disputes heard in Federal or Tribal courts, none want disputes resolved under State law in State courts. On the other hand, Section 19 would preclude Tribal jurisdiction and provide that disputes between the parties be governed by the laws of the United States and the State surrounding the applicable customer's Tribal lands. While Federal jurisdiction may be a compromise, the contract modification would authorize a Tribal customer and AmerisourceBergen to enter into a private commercial contract for Tribal direct-access to prime vendor services. Federal jurisdiction and the application of Federal law to disputes under such a contract is questionable; nor may the parties provide by contract for Federal jurisdiction if it does not otherwise exist. Rather than have this section prove a stumbling block to implementation of a direct-access relationship, we suggest that jurisdictional issues be discussed further and that binding arbitration be explored as an option.