Testimony of Mark Merritt

President & Chief Executive Officer
Pharmaceutical Care Management Association

Before the

UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
SUBCOMMITTEE ON THE FEDERAL WORKFORCE, U.S. POSTAL SERVICE, AND THE CENSUS

“The Federal Employees Health Benefit Program:
Is It a Good Value for Federal Employees?”

April 11, 2013
Introduction

The Pharmaceutical Care Management Association (PCMA) appreciates this opportunity to submit our statement for the record of the April 11, 2013 Subcommittee Hearing. PCMA is the national association representing America’s pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 216 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, Medicare, Medicaid, and the Federal Employees Health Benefits Program (FEHBP).

PBMs utilize a number of tools and strategies to manage prescription drug benefits that maximize value for health plan enrollees and PBM clients – employers, health plans, federal and state governments, and other payers. A common thread connecting all programs administered by PBMs is that success depends on offering the best overall value in terms of cost, quality, access, and convenience for health plan enrollees and saving PBM clients money. To stay in business, PBMs must deliver high-quality prescription drug benefits at highly competitive prices.

The FEHBP has long been the gold standard for employer-sponsored health benefits and is a model for health insurance reform efforts at the state and national levels. The hallmark of the FEHBP is consumer choice and competition. FEHBP offers a wide range of health insurance options for federal workers, retirees and their families and is extremely popular, with a recent Office of Personnel Management (OPM) survey showing that enrollees are satisfied with their benefits by a 7 to 1 margin. Like any large employer, OPM structures benefits to attract and retain talented employees. Comprehensive prescription drug coverage, widely available at retail and mail-service pharmacies, is a key component of benefit design in the FEHBP. Most plans that participate in the FEHBP competitively bid their drug benefit administration to PBMs.

OPM does not negotiate prescription drug prices or discounts directly with manufacturers or pharmacies, but instead uses its leverage with carriers to negotiate price concessions and reduce wasteful spending on prescription drugs for FEHBP enrollees. OPM’s annual carrier letter establishes parameters within which the health plans – and by extension their subcontractors, such as PBMs, dental benefit managers, and mental health benefit managers – must operate. OPM provides additional guidance on specific issues and practices it deems necessary to address. Through this process OPM encourages carriers to innovate and implement
new initiatives to address rising costs and stimulate appropriate use of health care goods and services.

In its most recent carrier letter, OPM encourages plans to innovate by making pharmacy benefits management a “central theme” of their 2014 proposals. The agency suggests that plans detail how they will use PBM tools such as tiered cost sharing, prior authorization, and step therapy to encourage the use of generics and more affordable brands. Likewise, OPM encourages plans to explore how to use preferred pharmacy networks, mail-service pharmacies, and specialty pharmacies to reduce drug costs. OPM specifically highlights the promise of innovative pharmacy networks, saying “We understand that members can achieve even greater savings on prescription drugs with minimal member disruption, through either a narrower pharmacy network or a preferred pharmacy network.”

OPM’s focus on pharmacy networks aligns with a recent PCMA study which found that greater use of preferred and limited pharmacy networks could save the U.S. health system $115 billion over the next ten years with minimal disruption to beneficiaries. The savings results from competition among the abundance of pharmacies in the United States, including those in big-box stores like Target and Walmart, in grocery stores, independent and chain pharmacies, and mail service pharmacies. Since there are over 60,000 retail pharmacies nationwide -- more than McDonalds, Burger Kings, Pizza Huts, Dunkin Donuts, Wendy’s, Taco Bells, Kentucky Fried Chickens, and Domino’s Pizzas combined -- preferred pharmacies can save money without reducing access for patients.

The OPM-established model for pharmacy benefits has allowed PBMs, working with FEHBP carrier clients, to create broad and convenient access to prescription drugs and generate significant savings for health plans and enrollees. Just as they do for private-sector health plans and large employers, PBMs participating in FEHBP plans play a key role in negotiating price discounts from manufacturers and pharmacies in order to lower unit drug prices.

Negotiating price concessions on drugs is just one of the many ways PBMs reduce pharmacy benefits costs. PBMs encourage higher generic utilization, employ more affordable delivery options such as mail-service pharmacy, negotiate discounts from retail pharmacies, and help doctors and patients understand when safer, more affordable options are available.
understand that the “unit price” of a drug is only one of many different components of prescription drug spending. To ensure added value of these services to payers, PBMs also provide choice of formularies, broad access to medications, convenient pharmacy options, and other benefits for enrollees.

These methods have proven to be successful in lowering the overall costs of drugs. According to the CMS National Health Expenditures Accounts, annual expenditures on outpatient prescription drugs have increased more slowly in the past four years than at any time in the previous four decades. In 2011, expenditures on prescriptions increased just 2.9 percent, well below the 3.9 percent rate of increase in health expenditures overall.

This trend is due in large part to a continued increase in generic dispensing from 67 percent in 2007 to 80 percent in 2011, which was encouraged by PBMs through lower or waived copayments and formulary compliance programs such as step therapy. Generic dispensing rates are generally higher in plans administered by PBMs than in other federal programs, especially Medicaid. This is significant, because every 1 percentage point increase in the generic fill rate can translate into a 1 percentage point reduction in drug costs.

PBMs have been studied by several federal agencies and have received excellent ratings on their performance. In general, the deeper the Federal Trade Commission (FTC) probed into the operations of PBMs and related entities, the more reassuring were the results. This was largely attributed to complex, robust, far-reaching, negotiation-driven competition. Reports from other federal agencies, including three reports from the Congressional Budget Office (CBO 2007a, 2007b, and 2008) and two from the Government Accountability Office (GAO 2003 and 2009), confirm this. The 2003 GAO report, for example, found that FEHBP enrollees paid the lowest prices for 30 prescriptions when purchasing through PBM-owned mail-order pharmacies.

Proposals to Change the Way FEHBP Purchases Pharmacy Benefits

Over the years, alternatives to alter the way OPM purchases and administers pharmacy benefits have been proposed. At the outset, let us note that OPM, through its contracts, already has the capability to implement almost any idea it thinks would improve the quality and value of the program. One proposal included in the President’s budget last year and, we assume, this year
would carve-out pharmacy benefits from all OPM’s 230 carriers and put the pharmacy benefit for the entire FEHBP program up for bid to the lowest bidder. PCMA takes a neutral position on this concept as our member companies differ in their views on it.

Other proposals, including Ranking Minority Member Lynch’s bill (H.R 1367), would impose drastic changes on the FEHBP program that would put at risk its ability to continue offering the savings, quality, and choice to which its enrollees have become accustomed. Some FEHBP “reform” proposals substitute federal price controls for market-based competition, while other proposals substitute congressional oversight for that of state boards of pharmacy.

For example, H.R. 1367 would forbid PBMs from paying more than the average manufacturer price for drugs, substituting instead government price controls. This would make the program look more like parts of Medicaid—where price-controls have led states to pay pharmacy dispensing fees which are often double or triple those paid in Medicare Part D and the commercial market. Part D, which, like FEHBP, relies upon competition not price controls, has consistently performed better than CBO projections. Part D is currently more than 40 percent under initial budget projections, has achieved beneficiary satisfaction rates close to 95 percent, and, according to the recent MedPAC report, had a low 2.9 percent annual growth rate in per capita spending from 2006 to 2010.

Such critical changes to FEHBP would normally follow a major report or significant findings that benefits are substandard or services are overpriced compared to other employer payers. But that is not the case. Beneficiaries are overwhelmingly satisfied with FEHBP, by a margin of 83 to 14. FEHBP benefit levels and premiums are comparable to or better than those received by employees in the private sector.

Some have suggested that FEHBP’s drug costs are significantly higher than those of private-sector employers, noting that drug benefits are a greater percentage of FEHBP’s total spending. But behind the figures are significant differences between FEHBP’s insured population and that of most employers. First, the federal workforce is ten years older than that of the average private sector employer, which makes it a heavier user of health care services in general, and prescription drugs in particular, than the average employee population. Second, the FEHBP figures also include expenses for FEHBP’s retiree population, including payments for
cost sharing for Medicare-eligibles. Again, retirees are higher users of prescription drugs than working populations. It is unclear whether these numbers also include the costs of the inpatient medications, which are different than outpatient costs. In combination, this largely explains the differences between FEHBP and the average employer expenditure on drug benefits.

Various proposals, including both the carve-out proposal and H.R. 1367, would set in statute contract requirements for PBMs participating in FEHBP. In H.R. 1367, PBMs would be required by statute to disclose proprietary contract terms regarding drug acquisition costs and pharmacy dispensing fees to OPM, carriers, and enrollees, as well as similar information on private-sector contracts outside of FEHBP. The bill would establish drug price controls with reimbursement based on the average price a manufacturer receives from wholesalers for a given drug and require uniform maximum pharmacy dispensing fees determined by OPM. These are functions that are currently subject to negotiation, and indeed, OPM has required through its contracting process that FEHBP carriers require information on drug acquisition costs, obviating the legislation. Further, the bill preempts state laws governing generic drug substitution and therapeutic interchange.

**Impact on Patient Safety and Drug Costs of Proposals Limiting Generic Substitution**

Pharmacy benefits are carefully designed by FEHBP carriers and their PBMs to give enrollees incentives to use high-value, cost-effective products. Typically this involves promoting generic substitution for branded drugs, within the limits of state law. Pharmacy and physician prescription practices are generally regulated by the States and developed by professional boards with clinical expertise. Some proposals, including H.R. 1367, would place restrictions on drug substitution for FEHBP enrollees. For example, the bill would not allow a drug substitution based on safety if the replacement drug were “higher in cost.” The drug-substitution provisions of H.R. 1367 represent a substantial shift in existing law and could significantly compromise patient safety. Any proposals including such a provision should be carefully weighed for these types of unintended consequences.

H.R. 1367 would also prevent pharmacies from substituting generic drugs without the approval of the prescribing doctor, despite state pharmacy laws requiring such substitution.
Generic drugs are widely accepted by patients – indeed, the reason drug costs are not increasing more rapidly is that many brands have lost patent exclusivity and are now competing against generics. The burden on physician offices to respond to pharmacy inquiries would be substantial and would add to physician workflow and overhead costs. In fact, physicians can already write “dispense as written” when they believe a patient would benefit from a specific drug in a therapeutic class. This bill could also cause longer lines at the pharmacy counter. Thus, the extensive patient and physician consultation and approval imposed by this kind of requirement would markedly restrict dispensing of FDA-approved generic versions of brand equivalents and drive drug costs up without improving quality. Generics have proven to be extremely effective at controlling costs and expanding access, which is why many states have implemented mandatory generic substitution laws.

**Impact on PBM Competition of Proposals to Debar or Limit Vertically Integrated PBMs**

Inexplicably, some proposals would limit the number of PBMs that could participate in the FEHB program. Competition keeps pressure on PBMs to negotiate well and keep costs down, and it makes little sense to limit the field of potential PBM participants, especially if OPM is considering awarding the entire benefit to a single PBM. By way of example, H.R. 1367 would prohibit any drug manufacturer or retail pharmacy from having a controlling interest, defined as 20 percent, in a PBM serving the FEHBP and would prohibit a carrier-controlled PBM from earning a profit, which would appear to include making an operating margin. We do not see how limiting competition would result in the best prices for the program.

Turning to disclosure, PCMA notes that the FTC has said that public disclosure of proprietary pricing information, or “transparency,” leads to higher – not lower – prices. Nonetheless, some proposals would require public release of negotiated rates, by requiring plans to send enrollees, for every prescription, the prices paid to manufacturers for drugs and to pharmacies for dispensing them. These prohibitions and disclosure requirements, combined with an additional requirement that PBMs serving FEHBP disclose specific acquisition costs and other pricing information on their entire book of business, would raise costs and severely limit the number of PBMs willing to participate in FEHBP while driving up drug costs.
PBMs may be unwilling to risk losing the pricing concessions negotiated with manufacturers and pharmacies for non-FEHBP accounts because of the disclosures to enrollees, carriers, and OPM required by the bill. In an ironic twist, reduced competition among PBMs, with the possibility of only a single PBM administering all FEHBP drug benefits, would leave remaining PBMs with little or no incentive to lower costs.

**Impact of Proposals for Cost-Plus Pricing Controls**

FEHBP relies upon consumer choice and competition rather than price controls to hold down costs and maintain flexible benefits. It is designed to take advantage of price competition among private sector competitors. H.R. 1367 would require carriers to limit payments for drug charges to Average Manufacturer Price (AMP) minus enrollee cost sharing. AMP is the price manufacturers charge wholesalers. The bill also requires PBMs to pay carriers 99 percent of all compensation received from manufacturers. Given that 90 percent of all pharmaceuticals are purchased through drug wholesalers – which to stay in business must charge pharmacies more than the price at which they acquire a drug – requiring reimbursement at AMP would result in PBM reimbursements that are lower than the pharmacy’s acquisition cost.

Without accounting for a wholesaler’s markup, pharmacies would carry a loss on every prescription, whether the pharmacy served as the PBM’s mail-service pharmacy or was a retail pharmacy. Retail pharmacies contested a provision of the Deficit Reduction Act of 2005 (DRA) that imposed requirements regarding use and disclosure of drug acquisition costs based on wholesaler invoices (not manufacturer prices to wholesalers), and provisions in both the House and Senate health care reform bills redefined the AMP, based on manufacturer price to wholesalers, and set a new federal upper payment limit at 175 percent of AMP to address pharmacy concerns.

Even assuming the AMP requirement is adjusted to a different benchmark rate, H.R. 1367 would lead to a cost-plus only pricing policy in FEHBP. Polls show that employers don’t want mandates that restrict their choice in this regard. Large employers such as OPM have the option to structure contracts using cost-plus pricing, and many choose not to do so. Although OPM currently encourages its FEHBP health plan to use cost-plus pricing, it could decide to
follow the path taken by other large purchasers which encourage PBMs to negotiate bigger discounts by allowing them to retain a portion of any extra savings.

**OPM Already Has the Authority to Impose Standards and Requirements**

OPM already has the authority to impose all of H.R. 1367’s provisions without seeking any new authority from Congress. OPM routinely uses its existing authority to impose new PBM contract requirements – *when it deems them helpful to the program*. Indeed, OPM has already required FEHBP carriers to insist that PBMs meet rigorous transparency and cost-savings standards – some quite similar to those in the bill. For example, in the 2012 standard contract for experience-rated HMOs, OPM requires contracting PBMs to meet an extensive set of standards, including disclosure, conflict-of-interest, and rebate pass-through requirements. These requirements are outlined in Attachment 1 to this testimony.

Carrier letters, FEHBP guidelines, and the FEHB Carrier Handbook are the appropriate vehicles for OPM to guide and monitor the practices of participating carriers and plans as well as their subcontractors.

**Conclusion**

FEHBP is successful because it relies on market forces and competition to deliver high quality benefits and services to its enrollees. We urge the Subcommittee to pursue policies that foster and encourage competition to keep drug costs and pharmacy benefits affordable in the FEHBP. We especially urge the Subcommittee to consider carefully the likely harm of proposals, including most of the provisions in H.R. 1367, that would impose federal price controls on drug products and pharmacy services, preempt state laws that assure cost-savings from generic substitution, limit competition, and require sweeping disclosures of pricing and proprietary business practices that could have the unintended effect of driving prices higher and stifling competition. The significant adverse impact of such changes on federal workers, retirees, and dependents who rely on the FEHBP should not be taken lightly.
By using PBMs’ management strategies proven in Medicare Part D and the commercial market, FEHBP carriers achieve significant savings for their enrollees in their drug benefits and provided wide access to medications and pharmacies at affordable prices. Additional savings for FEHBP could be obtained if OPM encouraged carriers to adopt even greater use of preferred pharmacy networks, home delivery, formulary tiering, step therapy, prior authorization, and other utilization management tools that facilitate cost-effective medication use.

PCMA looks forward to working with the Subcommittee and Congress to find additional ways to promote savings while continuing to deliver the highest quality, highest value prescription drug benefits for all federal employees.
attachment 1

federal employees health benefits program—
standard contract for experience-rated health maintenance organization carriers
2012

section 1.28
standards for pharmacy benefit management company (pbm)
arrangements (jan 2011)

the carrier will ensure and report that the following standards are included in new, renewing or amended contracts with vendors providing a retail pharmacy network and/or a mail order pharmacy and/or a specialty pharmacy to enrollees and dependents (hereafter “pbm”) effective on or after january 1, 2011. notwithstanding the foregoing, the revisions to section 1.28(a) in the january 2011 clause shall not take effect before the expiration of the carrier’s current contract (including the exercise of an existing option to extend the term by not more than one year at a time) but not later than january 2013. the pbm includes all entities that have a majority ownership interest in or majority control over the pbm. the pbm also includes any other subsidiary of the entity that has majority ownership or control over the pbm.

this section does not apply to carrier-owned pbms, which are already expected to adhere to the far and fehbar standards and requirements, and the remaining provisions of this contract.

(a) transparency standards

(1) the pbm is not majority-owned or majority-controlled by a pharmaceutical manufacturing company. the pbm must disclose to the carrier and opm the name of any entity that has a majority ownership interest in or majority control over the pbm.

(2) the pbm agrees to provide pass-through transparent pricing based on the pbm’s cost for drugs (as described below) in which the carrier receives the value of the pbm’s negotiated discounts, rebates, credits or other financial benefits.

(i) the pbm shall charge the carrier no more than the amount it pays the pharmacies in its retail network for brand and generic drugs plus a dispensing fee.

(ii) the pbm shall charge the carrier the cost of drugs at mail order pharmacies based on the actual cost, plus a dispensing fee. costs shall not be based on industry benchmarks; for example, average acquisition cost (aac) or wholesale acquisition cost (wac).

(iii) the pbm, or any other entity that negotiates and collects manufacturer payments allocable to the carrier agrees to credit to the carrier either as a price reduction or by cash refund the value all manufacturer payments properly allocated to the carrier. manufacturer payments are any and all compensation, financial benefits, or remuneration the pbm receives from a pharmaceutical manufacturer, including but not limited to, discounts; credits; rebates, regardless of how categorized; market share incentives, chargebacks, commissions, and administrative or management fees. manufacturer payments also include any fees received for sales of utilization data to a pharmaceutical manufacturer.
(3) The PBM must identify sources of profit to the Carrier and OPM as it relates to the FEHB contract.

(4) The PBM’s administrative fees, such as dispensing fees, must be clearly identified to retail claims, mail claims and clinical programs, if applicable. The PBM must agree to disclose sources of each administrative fee to the Carrier and OPM.

(5) The PBM, or any other entity that negotiates and collects Manufacturer Payments allocable to the Plan, will provide the Carrier with quarterly and annual Manufacturer Payment Reports identifying the following information. This information shall be presented for both the total of all prescription drugs dispensed through the PBM, acting as a mail order pharmacy, and its retail network and in the aggregate for the 25 brand name drugs that represent the greatest cost to the Carrier or such number of brand name drugs that together represent 75% of the total cost to the Carrier, whichever is the greater number:

(i) the dollar amount of Total Product Revenue for the reporting period, with respect to the PBM’s entire client base. Total Product Revenue is the PBM’s net revenue which consists of sales of prescription drugs to clients, either through retail networks or PBM-owned or controlled mail order pharmacies. Net revenue is recognized at the prescription price negotiated with clients and associated administrative fees;

(ii) the dollar amount of total drug expenditures for the Plan;

(iii) the dollar amount of all Manufacturer Payments earned by the PBM for the reporting period;

(iv) the Manufacturer Payments that have been (1) earned but not billed (2) billed and (3) paid to the PBM based on the drugs dispensed to the Plan members during the past year.

(v) the percentage of all Manufacturer Payments earned by the PBM for the reporting period that were Manufacturer Formulary Payments, which are payments the PBM receives from a manufacturer in return for formulary placement and/or access, or payments that are characterized as “formulary” or “base” rebates or payments pursuant to the PBM’s agreements with pharmaceutical manufacturers;

(vi) the percentage of all Manufacturer Payments received by the PBM during the reporting period that were Manufacturer Additional Payments, which are all Manufacturer Payments other than Manufacturer Formulary Payments.

(6) The PBM agrees to provide the Carrier, at least annually, with all financial and utilization information requested by the Carrier relating to the provision of benefits to eligible enrollees through the PBM and all financial and utilization information relating to services provided to the Carrier.

(7) The Carrier shall provide any information it receives from the PBM, including a copy of its contract with the PBM to OPM. A PBM providing information to a Carrier under this subsection may designate that information as confidential commercial information. The Carrier, in its contract with the PBM shall effectuate the PBM’s consent to the disclosure of this information to OPM. OPM shall treat such designated information as confidential under 5 C.F.R. § 294.112.

(8) If the Carrier’s PBM arrangement is with an Underwriter rather than with the Carrier, then all references to the Carrier and Plan appearing in this Section 1.28 shall be deemed to be references to the Underwriter.
(9) The Carrier will require that its PBM contractors:
   (i) Provide information to physicians, pharmacists, other health care professionals, consumers, and payers about the factors that affect formulary system decisions, including: cost containment measures; the procedures for obtaining non-formulary drugs; and the importance of formulary compliance to improving quality of care and restraining health care costs;
   (ii) Provide consumer education that explains how formulary decisions are made and the roles and responsibilities of the consumer; and
   (iii) Disclose the existence of formularies and have copies of the current formulary readily available and publicly accessible.

(10) In accordance with FEHBAR 1652.204-74, FAR 52.215-2 and FEHBAR 1652.246-70, all contracts and other documentation that support amounts charged to the Carrier contract are fully disclosed to and auditable by the OPM Office of Inspector General (OPM OIG). The PBM must provide the OPM OIG upon request all PBM records including, but not limited to:
   (i) All PBM contracts with Participating Pharmacies;
   (ii) All PBM contracts with Pharmaceutical Manufacturers;
   (iii) All PBM contracts with third parties purchasing or using claims data;
   (iv) All PBM transmittals in connection with sales of claims data to third parties; and
   (v) All PBM Maximum Allowable Cost (MAC) price lists.

(b) Integrity Standard
The Carrier will require that its PBM contractors agree to adopt and adhere to a code of ethics promulgated by a national professional association, such as the Code of Ethics of the American Pharmacists Association (dated October 27, 1994), for their employed pharmacists.

(c) Performance Standards
The Carrier will require that its PBM contractors develop and apply a quality assurance program specifying procedures for ensuring contract quality on the following standards at a minimum and submit reports to the Carrier on their performance. PBMs must meet, at minimum, the member inquiry, telephone customer service, paper claims processing, and other applicable standards set for Carriers at Section 1.9(g)(1), (3), (5) and (6). All other standards discussed below will have specific target goals the PBM is expected to achieve. Carriers may permit PBMs to measure compliance using statistically valid samples for the PBMs book of business. Agreed to standards shall be provided to OPM for its review and comment. If OPM has concerns about a particular standard, the Carrier agrees to present OPM’s concerns to the PBM and either revise the standard as requested by OPM or revise the standard to the extent feasible and present to OPM information demonstrating the problems associated with making the requested revisions in full.

(1) Retail Pharmacy Standards
   (i) Point of Service (POS) system response time. The PBM’s network electronic transaction system provides rapid response to network pharmacies.
   (ii) POS system availability. The PBM’s network electronic transaction system generally is available to, and accessible by, network pharmacies.
(iii) Licensing – The PBM verifies the appropriate licensing of its network pharmacies.

(2) Mail Service Pharmacy Standards

(i) Dispensing accuracy – The PBM dispenses its prescriptions to the correct patient and for the correct drug, drug strength and dosage in accordance with the physician’s prescription not less than 99.9% of the time.

(ii) Turnaround time – The PBM promptly dispenses and ships at least 98% on average of all prescriptions not requiring intervention or clarification within 3 business days or meets an equivalent measure approved by OPM.

(3) Prior Approval – if applicable – The PBM promptly reviews and responds to requests for prior approval for specific drugs following receipt of all required information.

(4) Quality of Drug Therapy - The quality assurance program implemented by a Carrier’s PBM contractor must include a process to measure the quality of its drug therapy provided to enrollees. Specific areas to be addressed include achievement of quality targets measured by both internal and external metrics; identification and appropriate use of best practices; and application of evidence-based medicine, as appropriate.

(d) Alternative Drug Options
The Carrier will require that its PBM contractors, at a minimum, utilize the following protocols for PBM initiated drug interchanges (any change from the original prescription) other than generic substitution:

(i) The PBM must treat the prescribing physician, and not itself, as the ultimate decision-maker. Furthermore, to the extent appropriate under the circumstances, the PBM must allow the patient input into that decision-making process. At a minimum, the PBM must provide the patient with a written notice in the package sent to the patient that the drug interchange has occurred with the approval of the Prescriber.

(ii) The PBM will obtain authorization for a drug interchange only with the express, verifiable authorization from the Prescriber as communicated directly by the Prescriber, in writing or verbally, or by a licensed medical professional or other physician’s office staff member as authorized by the Prescriber.

(iii) The PBM must memorialize in appropriate detail all conversations with patients and physicians in connection with drug interchanging requests, including the identity of the contact person at the physician’s office and the basis for his or her authority.

(iv) The PBM will only interchange a patient’s drug from a lower priced drug to a higher priced drug to patient or Plan when authorized by the Carrier or the Plan.

(v) The PBM will permit pharmacists to express their professional judgment to both the PBM and physicians on the impact of drug interchanges and to answer
physicians’ questions about dosing. PBM will not require pharmacists to, and will not penalize pharmacists for refusing to, initiate calls to physicians for drug interchanges that in their professional judgment should not be made.

(vi) The PBM will offer to disclose, and if requested, will disclose to physicians, the Carrier, and patients (i) the reason(s) why it is suggesting a drug interchange and (ii) how the interchange will affect the PBM, the Plan, and the patients financially.

(c) Patient Safety Standard - The Carrier will require that its PBM contractors establish drug utilization management, formulary process and procedures that have distinct systems for identifying and rectifying consumer safety issues including:

(i) A system for identifying and communicating drug and consumer safety issues at point-of-service; and
(ii) A system of drug utilization management tools, such as prospective and concurrent drug utilization management that identifies situations which may compromise the safety of the consumer.

(f) Safety and Accessibility for Consumers - The Carrier will require that its PBM contractors meet the following standards related to pharmacy network management and consumer access to medications.

(1) The Carrier will require that its PBM contractor define the scope of its services with respect to:
   (i) The distribution channels offered (e.g. pharmacy network, mail order pharmacies, or specialty pharmacies);
   (ii) The types of pharmacy services offered within each distribution channel; and
   (iii) The geographic area served by each distribution channel.

(2) The Carrier will require that for each distribution channel provided by its PBM contractor, the PBM contractor:
   (i) Establishes criteria and measures actual performance in comparison to those criteria; and
   (ii) Makes improvements where necessary to maintain the pharmacy network and meet contractual requirements.

(3) The Carrier will require that its PBM contractor establish a quality and safety mechanism for each distribution channel in order to identify and address concerns related to:
   (i) Quality and safety of drug distribution; and
   (ii) Quality of service

(g) Contract Terms - The contract between the PBM and the Carrier must not exceed 3 years without re-competition unless the Contracting Officer approves an exception. The Carrier’s PBM contract must allow for termination based on a material breach of any terms and conditions stated in the Carrier’s PBM contract. The Carrier must provide sufficient written notice of the material breach to the PBM and the PBM must be given adequate time to respond and cure the material breach.