Defense Health Agency (DHA) Determination on TRICARE Pharmacy Benefits Program Coverage for Prescriptions for Compound Pharmaceuticals

Background and Discussion.

The Military Health System's (MHS) top priority is quality and patient safety. Compound drugs are prescribed for MHS beneficiaries; however, over the past several years, there has been a tremendous increase in the number of compound pharmacy prescriptions, many of those lacking clinical or medical evidence of their safety or effectiveness. A system upgrade for pharmacy claim submissions in July 2012 by Express Scripts, Inc. (ESI) (TRICARE's Pharmacy contractor), gave DHA (formerly TRICARE Management Activity (TMA)) visibility of all ingredients contained in a compound drug claim including those bulk drug powders and chemicals that are not approved by the U.S. Food and Drug Administration (FDA) for commercial marketing. ESI completed an in-depth review of compound drug costs and usage in January 2013.

The DHA's highest obligation is to our patients – providing safe and effective care grounded in solid medical science. The Institute for Safe Medication Practices (ISMP), for example, recently reported that patients "may be unaware of the potential dangers" of certain pain cream medications and children may be accidentally exposed to products that are not properly labeled. (Designer Pain Creams and Ointments are Profitable for Compounding Pharmacies but Risky for Patients and Children, ISMP Safe Medicine, January/February 2015, Volume 13, Issue 1 at page 3.) 10 U.S.C. § 1074g(a)(1) mandates "an effective, efficient, integrated pharmacy benefits program" and permits a prior authorization (PA) process under 10 U.S.C. § 1074g(a)(4) for "certain pharmaceutical agents to ensure that the use of such agents is clinically appropriate." The Code of Federal Regulations (C.F.R.) reinforces this mandate providing that the Department of Defense (DoD) establish an effective and efficient pharmacy program under 32 C.F.R. § 199.21(a)(1). Also, consistent with the standards applicable to all products and services under TRICARE, under § 199.4(g)(15), if a drug "cannot be lawfully marketed without the approval" of the FDA "and approval has not been given," the safety and effectiveness of that drug is considered unproven and thus the drug "cannot be cost-shared" by TRICARE.

In addition to the obligation to provide a safe and effective pharmacy program, the DHA has an obligation to demonstrate that it is a responsible steward of taxpayer dollars. Compound drug costs have risen steeply with DoD spending $5 million in fiscal year (FY) 2004, increasing to over $514 million in FY14, and on pace to exceed $2 billion in FY 15. Compound drug costs in the month of January 2015 were $194 million compared to $35 million in January 2014 and $17 million in January 2013. Compound prescriptions account for just 0.5% of all DoD prescriptions but now account for over 20% of the total pharmacy spend. A closer look at the wholesale acquisition cost data reveals a remarkable range. Examples related to some of the leading compounded ingredients are: for flurbiprofen powder, a range from $.32/gram to $42.71/gram; for dextrose powder, a range from $.03/gram to $1,920.50/gram; for fluticasone propionate powder, a range from $123.50/gram to $3,197/gram; for mometasone furoate powder, a range from $147.05/gram to $20,859/gram; and for gabapentin powder, a range from $.70/gram to

$54.40/gram. Overall, the cost data suggest that the recent extraordinary growth in compound prescription costs is not attributable to clinical factors.

In April 2013, TMA decided to implement ESI's new screening capabilities and no longer reimburse for some ingredients found in compound drugs including bulk drug powders and chemicals that the FDA had not approved for commercial marketing. In June 2013, ESI sent letters to approximately 44,000 beneficiaries who had received a compounded medication containing at least one non-FDA-approved ingredient during the previous 90 days. The letter informed these beneficiaries that the new policy regarding compound drugs would be effective July 24, 2013. ESI also developed a telephone script that provided details about this change in response to questions from beneficiaries. Notification of this change regarding payment for compound drugs raised concerns by beneficiaries, industry groups and other stakeholders. Because of these concerns and before the new screening took effect, TMA delayed its implementation from July 2013 to February 2014. TMA updated its website and notified beneficiaries that it was re-examining its policy with respect to compounds. This delay gave TMA an opportunity to conduct further review and study of this proposed policy.

In December 2013, the DHA learned that the FDA intended to publish two lists with respect to compound drugs: one list of approved bulk drug substances and a second list of substances that presented demonstrable difficulties. The FDA sought public comment on these lists and gave the general public until March 4, 2014 to do so. In December 2013, because of this FDA action and the pending publication and review of the FDA qualifying lists, the DHA postponed the February 2014 implementation date of the enhanced screening process. As of March 3, 2015, the FDA has not published these two lists with respect to approved bulk drug substances and demonstrably difficult substances.

The DHA has closely monitored FDA action on compound drugs. This includes the FDA's guidelines and non-binding recommendations regarding compounding under Section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) and its draft guidance on current good manufacturing practice for registered outsourcing facilities under Section 503B of the FDCA, both of which were published in July 2014. Additionally, the Government Accountability Office (GAO) published a report in October 2014 (GAO-15-64, October 2014) that highlighted that TRICARE continued to pay for non-FDA-approved ingredients in compounds contrary to regulation. The GAO recommended that the DoD align its practices with existing regulations with respect to TRICARE or amend those regulations to allow for payment for some or all bulk drug substances in compounds. The GAO also compared TRICARE to the Department of Veterans Affairs (VA) in that report. The GAO noted on page 22 that the VA has a more restrictive payment practice with respect to compounds than TRICARE and that "VAMC pharmacies dispense a compounded drug prescription only if the beneficiary has a specific medical need that cannot be met by a commercially available drug and an alternative drug from the VA formulary has been given full consideration."

In November 2014, the DoD's Pharmacy and Therapeutics Committee (P&T) unanimously recommended a Prior Authorization (PA) for compound drugs. The P&T found that the PA would maintain accessibility for compound drugs when appropriate while allowing for needed

screening for non-FDA-approved ingredients. The minutes from the P&T's November meeting explained:

> "MHS expenditures for compounded medications are significant and increasing, and compounded medications have a high potential for inappropriate use. From June 2013 through May 2014, 140,000 beneficiaries filled 360,000 compounded prescriptions that totaled over $410 million in expenditures at the Retail Network and Mail Order POS. In an effort to decrease inappropriate use and ensure safety for beneficiaries, PA criteria were proposed." (Minutes at 14.)

The proposed PA criteria considered the diagnosis and the duration of the therapy; whether the patient tried commercially-available products; and whether there was a national drug shortage of an otherwise commercially-available product. On page 15 of the minutes, the PA provided specific criteria for the patient:

> (1) Each active ingredient(s) is/are a chemical entity of an FDA-approved drug for marketing in the United States AND the drugs have not been withdrawn for safety reasons from the U.S. market.
> (2) Each active ingredient(s) used in this compound is indicated by the FDA to treat the diagnosis provided.
> (3) An FDA-approved commercially available product is not appropriate because the patient requires a unique dosage form or concentration (e.g., inability to take a solid dosage form, dose based on age or weight) and/or an FDA-approved product cannot be taken due to allergies or contraindication.

In January 2015, the Beneficiary Advisory Panel (BAP) did not concur with the PA recommendation of the P&T in a 5-2 decision. The BAP members were concerned about the short implementation period and the lack of a clear plan for notification to beneficiaries of changes. It also noted the lack of statistics showing that our beneficiary population was using medications for diagnoses inconsistent with prescriptions. The BAP requested clarifications on some of the questions from industry representatives and noted that the P&T would benefit from a more in-depth analysis of how compounds are handled in other parts of the industry and whether evidence exists that shows adverse effects on persons currently receiving compounded medications. In January 2015, the Director, DHA, disapproved the P&T Committee's recommendation pending additional consideration of the BAP comments.

It is noteworthy that in December 2014, the President signed the FY 2015 National Defense Authorization Act (NDAA) into law. Section 704 of the NDAA created 10 U.S.C. § 1079c, which authorizes provisional coverage for a service or supply deemed to be widely recognized in the United States as safe and effective, even if it does not meet the normal test of proven safety and effectiveness. The provision includes a range of evidence the DoD can consider when making this determination including clinical trials, technology assessments, and opinions from national professional associations. Furthermore, it allows the DoD to establish or disestablish the terms and conditions of the provisional coverage and requires the DoD to promptly publish

on a publicly-accessible TRICARE website a notice of the provisional coverage for the service or supply including any terms and conditions.

Compound pharmaceuticals are an issue for other Government and commercial health plans as well. A recent GAO report (GAO-15-85, October 2014, page 16) stated: "For private health plans offered in the commercial market, officials from three insurers we spoke with told us that they generally do not pay for bulk drug substances used to make compounded drugs and pay only for those ingredients in the compound that are FDA-approved products under their prescription drug benefit." Regarding Medicare, the GAO (GAO-15-64, October 2014, pages 20-21) noted: "In contrast to TRICARE, [Medicare] Part D's payment practices for compounder drugs are more restrictive. As required by statute, under Part D, federal payments are not available for non-FDA-approved products—including bulk drug substances—and inactive ingredients used to make a compounded drug." Additionally, screens for prescription claims for coverage and cost and the use of a review process to consider individualized requests are widely-used industry practices. Consistent with this standard, TRICARE has a robust PA process for individualized treatment reviews and currently has 86 drugs with a PA option as part of the DoD Pharmacy Benefit Management process.

The DHA's Pharmacy Operations Division (POD) has closely monitored this progression of authorities regarding compounds. The DHA has kept its beneficiaries informed of its actions regarding compound drugs beginning with the June 2013 notification letter and its updated website and ESI phone call scripts to answer beneficiary questions. The POD has consulted with stakeholders and provides this amended Determination with respect to compound drugs. This Determination does not constitute a significant change of the TRICARE benefit. Rather, it adopts a process authorized by current statute and regulations and comparable to that already used for many pharmaceutical products. It modifies the November 2014 P&T recommendation in a number of respects, including implementation of an initial electronic screening for non-FDA-approved ingredients and other information, followed by a PA review process, if requested. This revised process will ensure patients have access to safe and effective medications, including compounds when appropriate, which are best suited to their individual needs. In cases in which a PA is denied, the denial will be an appealable initial determination subject to the usual appeals process including adequate notice of appeal rights and requirements under 32 C.F.R. §199.10.

The DHA's Communications Division has developed key outreach products for thorough notification of stakeholders including beneficiaries, the military services and Military Treatment Facilities (MTF), Congress and the general public. In addition to TRICARE website notification, the DHA will also notify impacted beneficiaries of this Determination via letter in March 2015.

Determination of the Director, DHA:

Following careful consideration, I modify the P&T Committee recommendation for compound prescriptions after considering the needs of our beneficiaries, the safety and efficacy of compounds, our need to be responsible stewards of taxpayer dollars, and the coverage allowed by the TRICARE program. I note the concerns raised by the BAP and approve the following plan that addresses the issues it has raised. In approving this plan, I have also considered input and suggestions from the compounding pharmacy industry.

I approve the following modification to the November 2014 recommendation of the P&T Committee and direct its implementation to ensure beneficiaries have sustainable access to appropriate compound medications. Compound prescription claims will be reviewed by an initial electronic screening and, when necessary, a PA process.

COMPOUND PRESCRIPTION INITIAL SCREENING PROCESS

(1) Each ingredient submitted for payment will be screened to ensure the ingredient is:

   a. Lawfully marketed in the United States;
   b. Considered safe and effective; and,
   c. Appropriate for the patient based on clinical need and cost effectiveness.

(2) ESI, the TRICARE contractor, will conduct this initial electronic screening (which will normally occur within seconds per the contractual agreement between DHA and ESI), of each ingredient submitted for payment in a prescribed compound medication in order to ensure compliance with (1)a., b. and c. above.

(3) ESI will also screen each ingredient submitted for payment in a compound medication claim in order to ensure the submitted cost does not exceed the pricing standard as established by ESI under its network agreement with compounding pharmacies.

In the event that the claim is not approved by the initial electronic screening as described above, the prescriber and/or pharmacist may substitute or remove a non-covered ingredient or adjust the submitted price. For any rejected claim, the prescriber can request a PA review by submitting appropriate documentation and supporting evidence to ESI. The PA process (which will in most cases occur within 5 days following receipt of necessary information per the contractual agreement between DHA and ESI) reviews compound prescription claims with respect to the specific needs of individual patients. The review ensures the ingredients of the compounds in those claims are lawfully marketed, safe and effective, and appropriate for the specific patient.

COMPOUND PRESCRIPTION PA PROCESS

(1) The following information will be required when submitting a request for a PA review:

   a. What is the diagnosis?

b. Has the patient tried commercially-available products for the diagnosis provided? Please state all products tried and relevant results of therapy.

c. Is there a current national drug shortage of an otherwise commercially-available product?

d. What is the proposed duration of therapy?

e. Is the prescription cost-effective either because it meets the pricing standard as established between ESI and its network pharmacies or because the cost is reasonable in the context of the clinical indication and circumstances?

f. Other information the requestor believes supportive of the request.

(2) The request will be evaluated to determine whether the ingredient(s) submitted for payment is/are lawfully marketed in the United States and is (are) considered safe and effective, e.g., each ingredient(s) submitted for payment is a chemical entity of a U.S. Food and Drug Administration (FDA)-approved drug for marketing in the United States AND the drug(s) have not been withdrawn for safety reasons from the U.S. market. Ingredients may meet these criteria by complying with a. or b., below.

a. The ingredients submitted for payment are approved by the FDA for commercial marketing; OR

b. (i) Pharmacies performing compounding or acting as outsourcing facilities under the provisions of Sections 503A and 503B, respectively, of the Drug Quality and Security Act will conform with the requirements specified in those provisions; AND

(ii) The ingredients of the compounds are proven safe and effective under TRICARE standards or meet the requirements for being widely recognized in the United States as being safe and effective. The provider and/or pharmacy requesting payment for such a compound will provide evidence to support the determination.

NOTE: Evidence that may be considered for this purpose will be consistent with examples provided in 10 U.S.C. § 1079c to include: clinical trials published in refereed medical literature; formal technology assessments; positions of national medical policy organizations, professional associations, and/or expert opinion organizations. Other sources may be submitted by the provider and/or pharmacy and can be considered as validated evidence as the DHA considers appropriate.

(3) The request will be considered appropriate for the patient based on clinical need if the prescriber submitted evidence supporting the therapy for this patient and that an FDA-approved, commercially-available product is not appropriate because the patient requires a unique dosage form or concentration or other clinical reason (e.g., inability to take a solid dosage form, dose based on age or weight, ineffectiveness of such products for the patient, presence of allergy or contraindication).

IMPLEMENTATION INFORMATION

This adds compound prescriptions to the ESI screening process comparable to that currently used for all other TRICARE prescription claims. The establishment of pricing standards is routinely used by commercial pharmacy payers and is already in place for many drugs covered under the TRICARE Pharmacy Benefit as part of the ESI pharmacy network agreement.

The denial of a PA for compounded pharmaceuticals will be an appealable initial determination that will follow the usual appeals process and will include adequate notice of appeal rights and requirements under 32 C.F.R. §199.10.

This updated claims process is to ensure safety and quality for TRICARE beneficiaries. While not a change in TRICARE benefits, we must inform affected beneficiaries, prescribers and pharmacies so we are best positioned to ensure TRICARE beneficiaries receive, without interruption, safe and effective medications including appropriate compounded products. In order to ensure maximum awareness of this screening process for compound prescriptions, DHA will send a letter to beneficiaries who have received a compound prescription in the last 30 days. This letter will update correspondence first sent to beneficiaries on this subject in June 2013. In addition, I have requested that ESI inform the retail network pharmacies in the network. I have further directed DHA Strategic Communications to provide assistance with informing prescribers and pharmacists in the MTFs and promptly publishing a notice on TRICARE's publically-accessible website of this decision regarding compound drug claims processing procedures.

In order to ensure effective notice, I am directing that notification begin no later than March 6, 2015 and that this enhanced screening process for compound prescriptions begin on May 1, 2015.

Douglas J. Robb, DO, MPH
Lieutenant General, USAF, MC, CFS
Director

Signed: March 11, 2015