Dr. George Jones, Chief
Pharmacy Operations Division

Defense Health Agency

DHA Pharmacy
MTF Update

September 17, 2014

Agenda

Agenda Item	Presenter
Update on DHA Pharmacy Initiatives	Dr. Jones
e-Prescribing Update	Henry Gibbs
CII Conversion of Hydrocodone	Col Spilker
DEA Ruling Update	LCDR Nguyen
P&T Committee Update	CAPT Downs
Specialty Pharmacy	MAJ Ridderhoff
Hepatitis C Utilization	CDR Devine
Telmisartan Update	MAJ Folmar
Compounding Updates	Dr. Jones
Questions	All

Update on DHA Pharmacy Initiatives

- Core Operational Initiatives / Program Initiatives

- Operational Initiatives – to ensure optimal function
  - 1. ***Transition*** – to develop an operational unit under DHA
    - Unit Manning / Position descriptions being reviewed
  - 2. ***Essential Processes***
    - Develop Central approach to managing Pharmacy Funds
    - Identify / Pursue clinical pharmacy support in care settings

Pharmacy Initiatives, continued

- Program Initiatives – Integrated System; Savings
  - 1. ***Move Select Maintenance Medications to Mail / MTF***
    - TRICARE For Life Pilot
    - Standard Prescription Transfer Process
    - Uniform staffing formula / augmentation process for MTFs
  - 2. ***Optimize MTF Capability and Capacity***
    - Develop Requirements for Central Refill Support
    - Optimize MTF to TMOP process
    - Implement e-Prescribing to MTFs from community providers

Pharmacy Initiatives, continued

- 3. ***Optimal MTF Use of Centralized Purchasing Rules***
  - Enhanced reporting driving to full automation
  - Improve communication of business rules / opportunities
  - Expand collaborative initiatives with Federal Partners
- 4. ***Fully Leverage Formulary Management Capability***
  - Business Process Reengineering
  - Improve Communication
  - Fully Integrate Clinical Practice Guidelines into Formulary Process and Outcome assessment

Pharmacy Initiatives, continued

- 5. ***Reengineer New Drug Addition to Formulary Status***
  - Proposed regulation; Tracking / medical necessity process
- 6. ***Centralize Pharmacy Automation Contracts***
  - Identify existing contracts
  - Articulate uniform automation requirements
  - Develop central acquisition strategy (Pending a relook)
- 7. ***Evaluate Future Role for Satellite Pharmacy Locations***
  - Collaborate with Health Plan Initiatives
  - Define requirements for satellite facilities / contracts
- Now new #8 – ***Implementation of DEA Rule***

TFL Pilot Patient Activity Summary of Trends

- Feb – June 2014 utilization: Mail Order ⬆ 11.8%; MTF ⬆ 1%; Retail ⬇ 5%

- Awareness of the TFL pilot has increased prompting many beneficiaries to send maintenance prescriptions directly to mail without filling at retail.
  - ❑ Over 35,000 prescriptions YTD have been filled this way.

- Beneficiaries are also moving their non-targeted drugs to mail
  - ❑ YTD over 470,000 prescriptions have moved to mail.
  - ❑ In July 2014, over 94,000 prescriptions for non-targeted drugs (from 45,000 TFL patients) moved

- The TFL pilot program continues to identify beneficiaries who had not previously reported having OHI. YTD, over 1,900 beneficiaries have subsequently reported OHI eligibility impacting almost 3,000 medications.

Source: ESI's TFL Pilot Monthly Summary Contract Report

Polling Question

What is the next Pharmacy Shared Service policy that would be valuable to the field?

A. Controlled medications
B. Sole provider
C. Disposal of pharmaceuticals
D. Other (chat suggested policy topic)

e-Prescribing Update

- DoD eRx Initiative
  - Defense Health Agency (DHA), Pharmacy Operations Division (POD) initiative
    - Collaboration with Pharmacy Shared Services
  - Enables civilian providers to electronically transmit prescriptions to MTF pharmacies
- NH Bremerton →test site for eRx
  - Testing completed → August 25, 2014
- Implementation/Training
  - July/August 2014: eRx sessions were provided to MTF pharmacies
    - Focused on training, implementation plan, and lessons learned from NH Bremerton
  - Documentation → Training (PowerPoint slides &User Guide), Implementation guide, CHCS Release notes, Communication flyers
    - Disseminated via PEC Website

e-Prescribing Update

- POD is working with BE&S on Communication Plan
  - Focus on national outreach strategy, once eRx is available at all US locations
  - Local MTF outreach
    - Patient outreach → Flyers available for MTFs
      - Inform patients that your MTF is accepting electronic prescriptions
      - Educate them about the e-prescribing process
    - Provider outreach → Flyers available for MTFs
      - Inform providers that your MTF can accept electronic prescriptions
      - Ensure local MTF pharmacy formularies are published & provide location (e.g. website)
    - Articles, social media, local MTF website, etc.

e-Prescribing Update

- Roll-out is scheduled for September 2014:
  - September 19: Target date to begin installation of eRx software to MTFs
    - Software will be deployed over a 4-5 week period
    - Implementation will be spread-out over a few months
  - POD will coordinate with the MTFs (on each CHCS host) regarding the implementation tasks necessary to activate the eRx capability; this will include a DHA eRx Guidance document
- Dec 31, 2014: target date for completion of implementation

Hydrocodone- Schedule Conversion

- The Drug Enforcement Administration (DEA) conducted an evaluation, reviewed data, and the recommendation from Health and Human Services (HHS) to reschedule hydrocodone combination products (HCPs)
  - HCPs present substantial potential for abuse, a significant risk for diversion, and amounts are sufficient to be hazardous or unsafe
- DEA published, "Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II" on August 22, 2014
  - Substances affected are listed in 21 CFR 1308.13(e)(1) (iii) and (iv)
  - Effective Date: October 6, 2014
  - HCPs prescriptions issued before October 6, 2014 and authorized for refilling, may be dispensed before April 8, 2015.

Disposal of Controlled Substances

- The most current DoD Suicide Event Report (DoDSER), 2011 indicated a large percentage of suicide attempts involved prescription medications
  - The Drug Enforcement Administration (DEA) did not include language in their regulation to allow an ultimate user to return controlled substances to DEA registrants
    - Beneficiaries were not able to return their unwanted, unused, or expired controlled substances to pharmacies
  - A medication take-back program can securely and easily reduce access to prescription medications by providing Service members and their families the opportunity to dispose of medications that could be used for suicide or suicide attempts

Disposal of Controlled Substances

- On September 9, 2014, the DEA released their Final Rule, Disposal of Controlled Substances
  - Effective on October 9, 2014
  - Hospital/clinics with an on-site pharmacy can be "collectors"
    - MTF pharmacies registered with the DEA can be collectors
  - Collectors can have mail-back programs and collection receptacles
    - Drug take back events must have Federal, State, tribal, or local law enforcement present
- DoD Drug Take Back Efforts
  - Drug Take-back work group members from the Services, C&PP, and Pharmacy are working together to
    - Develop Directive-type Memorandum, directing the Services to have drug-take back programs
    - Develop Operational Guidance for implementation

May 2014 P&T Committee Update

Nasal Allergy Drugs: Formulary Status

Basic Core Formulary (BCF)	Uniform Formulary (UF)	Non-formulary (NF)
Nasal Steroids:	**Nasal Steroids:**	**Nasal Steroids:**
Fluticasone (Flonase generic)	Flunisolide (Nasarel generic)	Beclomethasone (Beconase AQ, QNASL)
	Antihistamines:	Budesonide (Rhinocort Aqua)
	Azelastine (Astelin generic)	Ciclesonide (Omnaris, Zetonna)
	Anticholinergics:	Fluticasone propionate (Veramyst)
	Ipratropium (Atrovent generic)	Mometasone (Nasonex)
		Triamcinolone (Nasacort AQ) - OTC
		Antihistamines:
		Azelastine in sucrose (Astepro)
		Olopatadine (Patanase)
		Antihistamines/Steroid:
		Azelastine/Fluticasone (Dymista)

- *Step preferred* (must try a UF agent first): fluticasone propionate (generic Flonase), ipratropium (generic Atrovent), flunisolide (generic Nasarel), azelastine (generic Astelin)
- *Step non-preferred (and NF)*: All other branded agents to include azelastine (Astepro), beclomethasone, budesonide, ciclesonide, fluticasone furoate, mometasone, olopatadine, and fluticasone/azelastine combination
- Step therapy applies to new & current users who are older than 4 years of age

Nasal Allergy Drugs: Key Points

- ***Nasal corticosteroids are first line agents*** in reducing nasal symptoms of congestion, rhinorrhea, congestion, and itching
- Nasal antihistamines are generally less effective than nasal corticosteroids for treating AR, but ***may be considered for use as first line therapy for AR and non allergic rhinitis***
- Nasal allergy drugs are clinically interchangeable, and generics meet the clinical needs of DoD patients

Inhaled Corticosteroids: Formulary Status

Basic Core Formulary (BCF)	Uniform Formulary (UF)	Non-formulary (NF)
• Fluticasone DPI (Flovent Diskus) • Fluticasone HFA MDI (Flovent HFA)	• Budesonide inhalation solution (Pulmicort Respules, generic)	• Beclomethasone HFA MDI (QVAR) • Budesonide DPI (Pulmicort Flexhaler) • Ciclesonide HFA MDI (Alvesco) • Mometasone DPI (Asmanex Twisthaler) • Flunisolide HFA (Aerospan)

- *Step preferred* (must try first)*:* fluticasone (Flovent HFA or Flovent Diskus)
- *Step non-preferred (and NF):* beclomethasone, budesonide, ciclesonide, flunisolide, mometasone
- Grandfathering applies - current users are NOT affected by the step
- All new users > 12 years are required to undergo step therapy; must try Flovent Diskus or Flovent HFA first
- Budesonide nebs (Pulmicort, generic) – not affected; remains UF & not subject to step therapy

Inhaled Corticosteroids: Key Points

- Insufficient evidence to suggest one ICS is superior to another
- Maintains same ICS that's in the preferred ICS/LABA (Advair)
- Asthma
  - ICS do not differ with regards to symptom control, need for rescue medication, and exacerbations in patients with asthma
- COPD
  - There is insufficient evidence to determine clinically relevant differences regarding the efficacy of ICS in patients with COPD
- Safety
  - There is insufficient evidence to determine clinically relevant differences between ICS in terms of minor adverse events or systemic adverse event

Oral Bisphosphonates: Formulary Status

Basic Core Formulary (BCF)	Uniform Formulary (UF)	Non-formulary (NF)
• Alendronate	• Ibandronate (Boniva)	• Alendronate/Vitamin D (Fosamax + D) • Risedronate (Actonel) • Risedronate delayed-release (Atelvia) • Alendronate effervescent tablet (Binosto)

- *Step preferred* (must try first)*:* Alendronate
- *Step non-preferred (but UF):* ibandronate (Boniva); grandfathering applies - current users are NOT affected by the step
- *Step non-preferred (and NF):* alendronate/vitamin D (Fosamax + D) and alendronate effervescent tablet (Binosto); risedronate (Actonel) and risedronate delayed-release (Atelvia); **NO** grandfathering (both new and current users are required to have tried alendronate)

Oral Bisphosphonates: Key Points

- All agents increase bone density similarly
- Relative superiority of one agent vs. another cannot be determined by BMD data alone
- Insufficient evidence to suggest one agent is superior to another
- Atelvia (delayed released risedronate) and Binosto (effervescent alendronate) offer no clinically compelling advantages over existing generic UF agents
- The FDA issued a guidance document pertaining to bisphosphonates and adverse events
  http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/drugs/DrugSafetyandRiskManagementAdvisoryCommittee/ucm270958.pdf

New Drugs

- 7 new drugs in previously reviewed classes
  - Of these, 4 failed to show an advantage (in terms of clinical or cost effectiveness) over formulary agents and were designated non-formulary
    - Budesonide MMX (Uceris) – for mild to moderate UC
    - Indacaterol (Arcapta) oral inhaler – long-acting beta agonist (LABA) for COPD
    - Dapagliflozin (Farxiga) - SGLT2 antidiabetic
    - Low dose diclofenac (Zorvolex) – mild to moderate pain
  - 3 new drugs were added to the Uniform Formulary

Sofosbuvir (Sovaldi)

HCV Drugs in the Class

Generic	Brand (Manufacturer)	Strengths & formulations	Initial FDA approval	Patent Expiration
Direct Acting Agents				
Boceprevir	Victrelis (Merck)	200 mg capsules	5/13/11	2022-2027
Telaprevir	Incivek (Vertex)	375 mg tablets	5/23/11	2025
Simeprevir	Olysio (Janssen)	150 mg	11/22/2013	
Sofosbuvir	**Sovaldi (Gilead)**	**400 mg**	**12/6/2013**	
Ribavirin and Interferons				
PEGInterferon alfa-2A	Pegasys (Genentech)	180µg/vial, 180µg /5ml	11/16/02	2017
PEGInterferon alfa-2B	PEGIntron (Merck)	50µg/0.5mL, 80µg/0.5mL, 120µg/0.5mL, 150µg/0.5mL—vials and syringes	1/19/01	2015[1]
Ribavirin	Rebetol (Merck); Copegus (Genentech); other generics	40 mg/mL Oral solution, 200/400/500/600 mg tablets, 200 mg capsules		2017 2023 (oral solution)

Sofosbuvir (Sovaldi)

- New molecular entity / breakthrough therapy designation
- Prodrug of a nucleotide (uridine) analogue inhibitor of the HCV NS5B RNA-dependent RNA polymerase
  - Uridine is not utilized in humans
- High barrier to resistance (S282T mutation)
- FDA indications
  - Sovaldi efficacy established in HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma awaiting liver transplantation and those with HCV/HIV-1 co-infection
  - Can use without interferon (IFN) – genotype 1, 2, 3
- Studied in multiple populations including interferon ineligible / intolerant
- Not studied in a protease inhibitor failure population
- **New standard of care**

Sofosbuvir (Sovaldi) Indications & Efficacy Summary

HCV genotype	Treatment	Duration	SVR / Cure
Genotype 1	SOFOSBUVIR + peginterferon alfa + ribavirin	12 weeks	90%
Genotype 1 IFN ineligible	SOFOSBUVIR + ribavirin *SOFOSBUVIR + SIMEPREVIR +/ -ribavirin**	24 weeks 12 weeks	76% 93-96%
Genotype 2	SOFOSBUVIR + ribavirin	12 weeks	95%
Genotype 3	SOFOSBUVIR + ribavirin	24 weeks	93% naïve 77% experienced
Genotype 4	SOFOSBUVIR + peginterferon alfa + ribavirin	12 weeks	96%
Hepatocellular carcinoma awaiting transplant	SOFOSBUVIR + ribavirin	up to 48 weeks or at transplant	64%

**Regimen not FDA approved*

Sofosbuvir (Sovaldi) Formulary Placement

- Decision
  - UF: sofosbuvir (Sovaldi)
  - Encourage pts to fill Rxs at Mail or MTFs
  - Add sofosbuvir and the Direct Acting Agents to the Specialty Drug Program to facilitate Retail → Mail recapture

- Justification
  - New standard of care per AASLD/IDSA guidelines
  - Better efficacy, lower risk of adverse events than telaprevir (Incivek) and boceprevir (Victrelis)
  - Large price differential between Mail Order/MTFs and Retail

No Longer Standard of Care

Remove Telaprevir (Incivek) from ECF

- Decision
  - ❑ Remove telaprevir (Incivek) from the ECF; remains UF
  - ❑ Do not designate any Direct Acting Agent on the ECF
  - ❑ Hep C drugs remaining on the ECF:
    - PEG-interferon lfa-2a (Pegasys)
    - Ribavirin 200 mg capsules (generics); excludes Ribapak formulation
- Justification
  - ❑ Incivek is no longer standard of care; although FDA approved, is markedly inferior to preferred and alternative regimens
  - ❑ New agents in pipeline likely to be candidates for ECF once approved

HCV Direct Acting Agents
Prior Authorization (PA)

- Applies to all new users
- Current users not affected by PA – can continue therapy
- Age ≥ 18
- Sofosbuvir (Sovaldi) / simeprevir (Olysio)

HCV genotype	Treatment	Duration	SVR / Cure
Genotype 1	SOFOSBUVIR + peginterferon alfa + ribavirin	12 weeks	90%
Genotype 1 IFN ineligible	*SOFOSBUVIR + SIMEPREVIR +/- ribavirin*	12 weeks	93-96%
Genotype 2	SOFOSBUVIR + ribavirin	12 weeks	95%
Genotype 3	SOFOSBUVIR + ribavirin	24 weeks	93% naïve 77% experienced
Genotype 4	SOFOSBUVIR + peginterferon alfa + ribavirin	12 weeks	96%
Hepatocellular carcinoma awaiting transplant	SOFOSBUVIR + ribavirin	up to 48 weeks or at transplant	64%

- Revised telaprevir and boceprevir prior authorizations

Apixaban (Eliquis)

Oral Anticoagulant Class

Generic Name	Brand Name (Mfg)	Formulations	FDA Approval	Patent Expiration
Vitamin K Antagonists				
Warfarin	Coumadin	1, 2, 2.5, 3, 4, 5, 6, 7.5, 10 mg tabs	Jun 1954	-
Direct Thrombin Inhibitors				
Dabigatran	Pradaxa (BI)	75, 150 mg caps	Oct 2010	2018-2027
Factor Xa inhibitors				
Rivaroxaban	Xarelto (J&J)	10, 15, 20 mg tabs	Jun 2011	2020-2021
Apixaban	Eliquis (Pfizer/BMS)	2.5, 5 mg tabs	Dec 2012	2019-2023

Oral Anticoagulants: FDA Indications

	Warfarin	Dabigatran	Rivaroxaban	Apixaban	Enoxaparin
Stroke prevention non-valvular Afib	X	X (Oct 2010)	X (Nov 2011)	X (Dec 2011)	
VTE prophylaxis	X				
Hip & Knee	X		X (Jul 2011)	X (Mar 2014)	
Hip fx	X				
VTE treatment (DVT/PE)	X	X (Apr 2014) +LMWH 5-10d	X (Nov 2012)	X (Aug 2014)	PE : In-pt DVT: Out-pt
↓ risk of recurrent PE/DVT	X	X (Apr 2014)	X (Nov 2012)	X (Aug 2014)	
Stroke prevention s/p cardiac valve replacement	X				
↓ death/recurrent MI/stroke after MI	X				

*** Enox: VTE prophylaxis medically ill pts & general surgery (abdominal); Cardiac**

Apixaban (Eliquis): Clinical Conclusion

- Apixaban is the 2nd factor Xa inhibitor to reach the market.
- Apixaban, like the other NOACs, has advantages of
  - predictable anticoagulant effect
  - fixed dosing
  - fewer drug interactions compared to warfarin
- All the NOACs offer a convenience to patients
  - laboratory monitoring for efficacy
  - dietary restrictions are not required
  - more data is needed in patients with renal and hepatic impairment
- In non-valvular AFib, apixaban showed
  - superiority to poorly controlled warfarin at preventing stroke
  - significant reduction in mortality, although the confidence interval approached
  - Significantly reduced intracranial bleeding and major bleeding

Apixaban (Eliquis): Clinical Conclusion

- For VTE
  - Non-inferior to LMWH/warfarin for reducing risk of recurrent VTE/VTE-related death; significantly less bleeding compared to warfarin
  - Benefits were shown with apixaban vs. placebo for extended treatment of VTE, with no difference in bleeding
- Orthopedic surgery prophylaxis, apixaban was
  - Non-inferior to enoxaparin 40 mg QD at reducing VTE with no difference in bleeding
- Discontinuing apixaban in inadequately anticoagulated patients increases the risk of thrombotic events in those with nonvalvular atrial fibrillation
- Patients require education and clinical monitoring to ensure appropriate use and avoid adverse reactions
- Full class review and potential BCF selection of a newer oral anticoagulant in 2015; awaiting FDA-approval of edoxaban

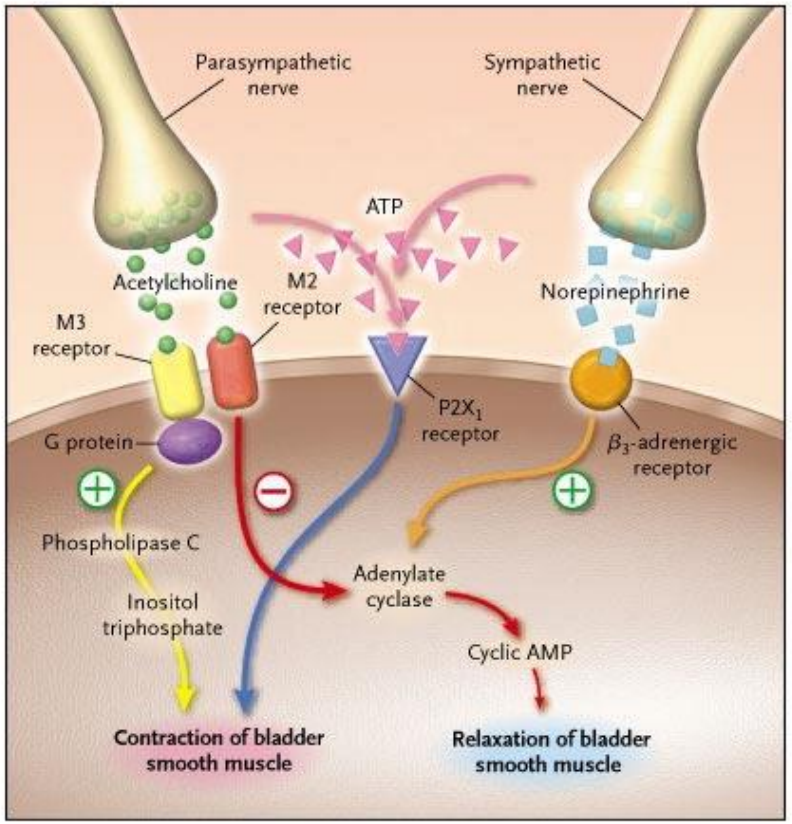
Apixaban (Eliquis): Formulary Placement

- Decision
  - UF: apixaban (Eliquis)

- Justification:
  - Clinically shows benefits for stroke prevention in Afib, VTE treatment, and for VTE prophylaxis in orthopedic surgery
  - Cost effective vs. the other NOACs

Mirabegron (Myrbetriq) for Overactive Bladder

- β3-adrenoreceptor agonist activity – new molecular entity (NME) in the class
- Step therapy implemented in Nov 2012; must try cost-effective generic or Detrol LA first
- Prior Authorization placed on Mirabegron in Feb 2014; implementation on 11 June 2014



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Mirabegron (Myrbetriq): Clinical Conclusion

- Mirabegron is a new molecular entity that is effective in the management of OAB
- Mirabegron 50 mg achieved efficacy objective when compared to placebo
  - Reduction 0.55 micturition / 24hr
  - Reduction 0.40 incontinence episode / 24hr
- There is insufficient direct evidence comparing mirabegron to other OAB drugs, but it does not appear different from the anticholinergic agents
- Mirabegron is well tolerated with the most common ADE including HTN, nasopharyngitis and UTI; dry mouth and other anticholinergic effects were reported less frequently in mirabegron than tolterodine
- Mirabegron has not been studies in cognitively impaired individual or other high risk fall population
- In the MHS, mirabegron mean MPR at 180 days is about 72%, vs. 61% with other agents
- Discontinuation rates are similar to other OAB drug and no persistence data has been published

Mirabegron (Myrbetriq): Formulary Placement

- Decision:
  - UF and step non-preferred: mirabegron (Myrbetriq)
  - Grandfathering for step therapy – all new users will hit step

- Justification
  - Mirabegron is more costly than the OAB step preferred drugs, but has a different adverse event profile that does not include anticholinergic effects
  - Due to the large number of current users who were not affected by the OAB step therapy recommended at the November 2012 meeting, current users are grandfathered

Self-Monitoring Blood Glucose Systems (SMBGS) Test Strip Update

- August 2013, P&T Committee reviewed SMBGS with recommendations to be implemented on 7 May 2014
- Implementation delayed due to GAO protest
- On 27 August 2014, the Court of Federal Claims issued a *permanent injunction* setting aside DHA's BPA bids
- SMBG test strips will be re-evaluated at an upcoming DoD P&T Committee meeting

MTF Communication

- May DoD P&T Committee MTF Formulary Management Documents will be forthcoming for the following:
  - Inhaled Corticoid Steroids
  - Nasal Allergy Drugs
  - Osteoporosis Drugs
- Feb DoD P&T Committee MTF Formulary Management Documents sent to the field last week of August for the following:
  - Inhaled Corticosteroids/Long-Acting Beta Agonist Combinations
  - GI-1 drugs – 5-Aminosalicylates (mesalamine products)

DoD P&T Committee

Upcoming Evaluations

August 2014

- UF Class reviews
  - Targeted Immunomodulatory Biologics (TIBs)
- New drugs
  - Non-insulin DM drugs, GLP1-RAs: albiglutide injection (Tanzeum)
  - ADHD: methylphenidate ER oral suspension (Quillivant XR)

November 2014

- UF Class review
  - Pulmonary Artery Hypertension
  - Multiple Sclerosis
  - V-Go
  - Blood Glucose Test Strips
- New Drugs
  - COPD drugs: umeclidinium/ vilanterol (Anoro Ellipta)
  - Ophthalmic NSAIDs: bromfenac (Prolensa)
  - Glaucoma: brimonidine/ brinzolamide (Simbrinza)

Specialty Pharmacy

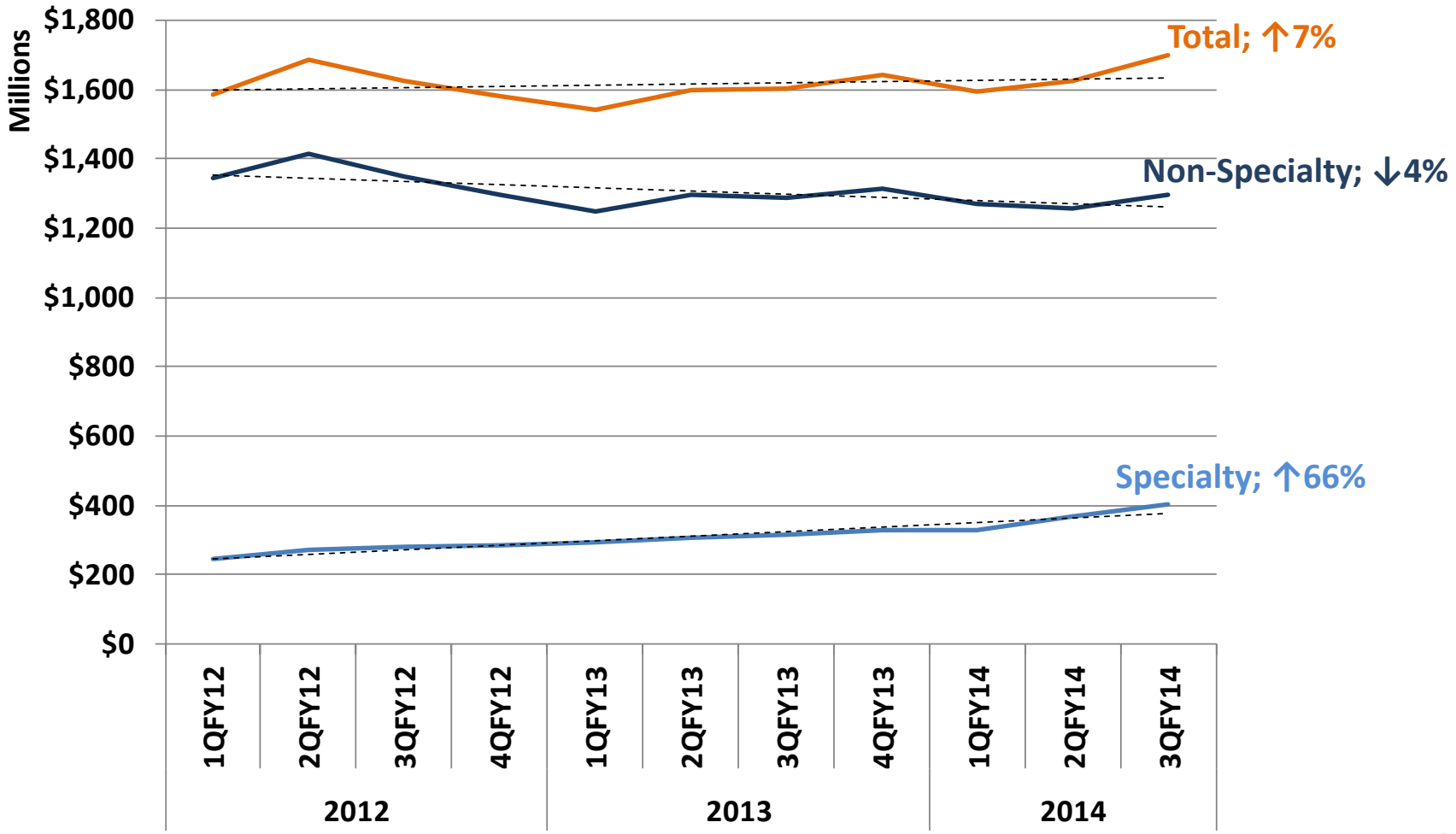
Specialty Medications
Background

- No industry standard definition of specialty
- US specialty drug spending projected to quadruple by 2020 to $402B per year
- Top 3 specialty therapy classes FY13: oral oncology agents; inflammatory conditions (targeted immunomodulatory biologics); multiple sclerosis
- MHS spent $1.2B in FY13 (19% of total spend)

Specialty Agent Definition
(for Reporting Purposes)

- A product can be classified as a DOD Specialty Agent if it meets at least two of the following:
  - ❑ Costs $500 or more per dose or $6,000 or more per year;
  - ❑ Difficult or unusual process of delivery;
  - ❑ Requires patient management beyond traditional dispensing practices;
  - ❑ As defined by DOD
- Standard definition for reporting and monitoring
- Begin analysis on optimizing this new drug "class" across all points of service

Increases in Overall Spend 3QFY14 vs. 1QFY12

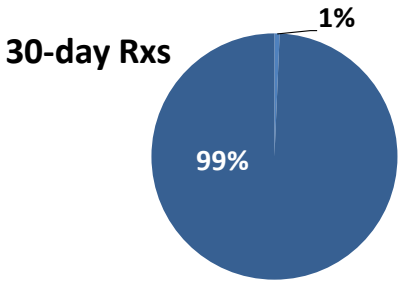


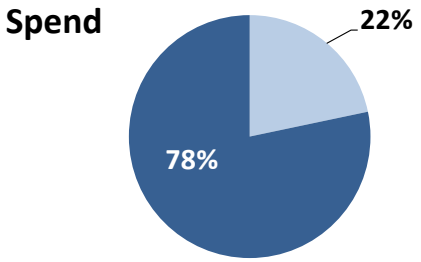
Refund-adjusted (estimated); omits paper claims, compounds, COB claims, OTC; based on 2QFY14 Specialty Agent Reporting List

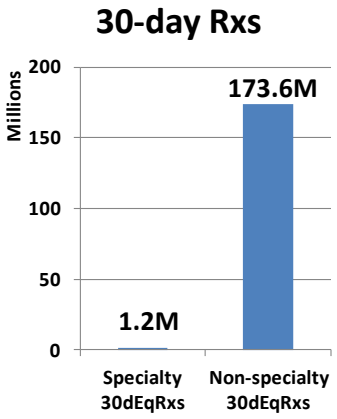
Specialty vs. Non-Specialty Spend

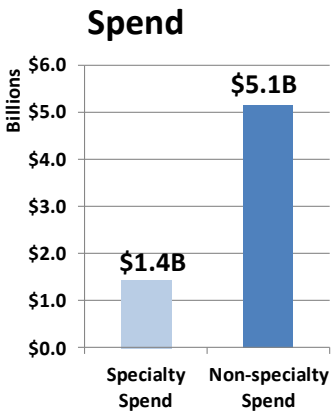
By Beneficiary Category

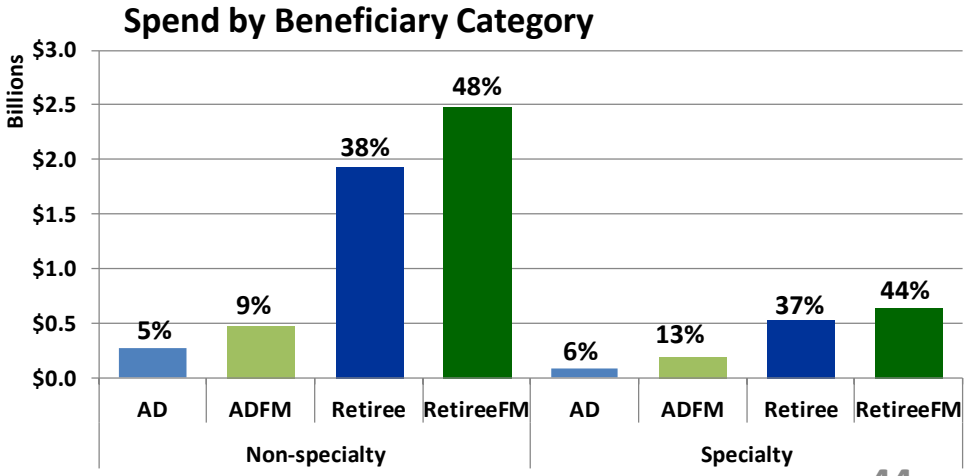
Row Labels	4Q FY13	1Q FY14	2Q FY14	3Q FY14	Grand Total ($M)
Specialty					
AD	$19	$19	$21	$23	$82
ADFM	$45	$44	$50	$51	$191
Retiree	$117	$119	$136	$152	$524
RetFM	$146	$144	$160	$178	$628
	$327	**$326**	**$368**	**$404**	**$1,424**
Non-specialty					
AD	$65	$64	$68	$67	$265
ADFM	$120	$111	$116	$118	$465
Retiree	$495	$482	$470	$482	$1,930
RetFM	$634	$612	$603	$630	$2,479
	$1,315	**$1,270**	**$1,256**	**$1,297**	**$5,139**
Grand Total	**$1,642**	**$1,596**	**$1,624**	**$1,701**	**$6,563**











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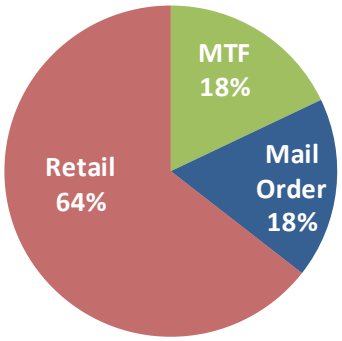
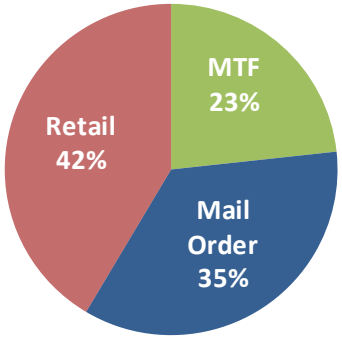
Specialty vs. Non-Specialty Spend
By POS

Row Labels	4Q FY13	1Q FY14	2Q FY14	3Q FY14	Grand Total ($M)
Specialty					
MTF	$56	$58	$68	$74	$256
Mail Order	$53	$53	$63	$81	$250
Retail	$218	$215	$236	$250	$918
	$327	**$326**	**$368**	**$404**	**$1,424**
Non-specialty					
MTF	$293	$285	$304	$315	$1,197
Mail Order	$436	$458	$427	$492	$1,813
Retail	$586	$527	$526	$490	$2,129
	$1,315	**$1,270**	**$1,256**	**$1,297**	**$5,139**
Grand Total	**$1,642**	**$1,596**	**$1,624**	**$1,701**	**$6,563**

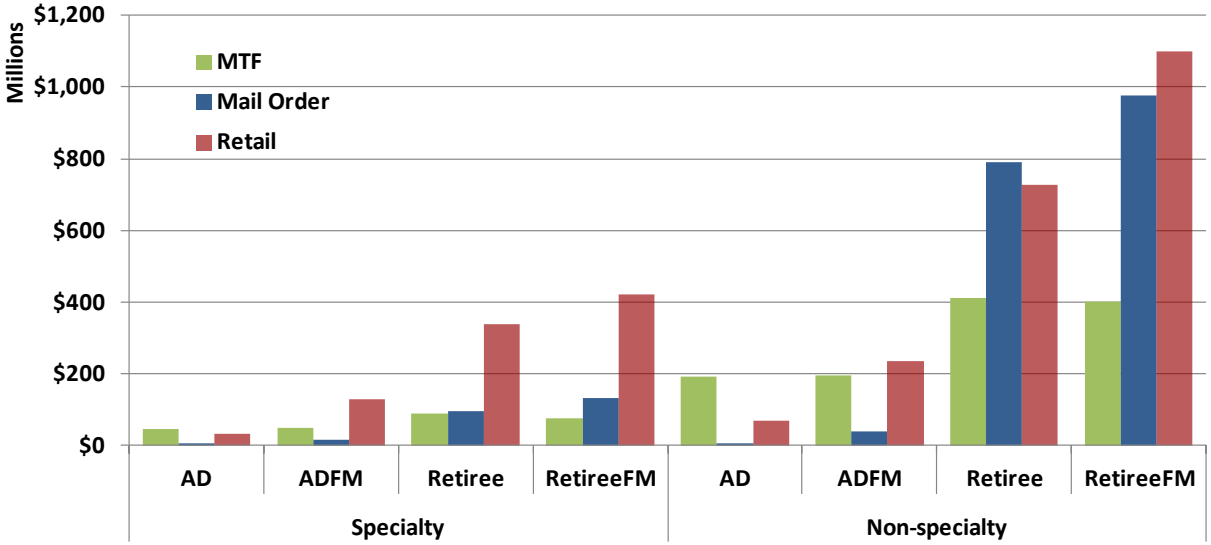
Specialty Spend



Non-Specialty Spend



Beneficiary Category by POS



Refund-adjusted (estimated); omits paper claims, compounds, COB claims, OTC; based on 2QFY14 Specialty Agent Reporting List

Top 20 Specialty Drug Categories

All POS, by 2QFY14 Total Spend for Specialty Agents

Categories	Cost 2QFY14 ($M)	
ONCOLOGICAL	$97.4	55%
TIBs	$65.3	
MULTIPLE SCLEROSIS	$53.3	
HEPATITIS C	$25.8	
ANTIRETROVIRALS	$18.2	
RESPIRATORY MISC (PAH)	$16.7	
ANTIHEMOPHILIC FACTORS	$14.1	
ENDOCRINE (corticotropin, cinacalcet)	$10.0	
ANTICOAGULANTS (LMWH)	$9.2	
GROWTH STIMULATING	$6.8	
IMMUNOLOGICAL –MISC (infusion/injectables)	$6.7	

Categories	Cost 2QFY14 ($M)
NEUROLOGICAL –MISC (mostly botulinum)	$6.7
OSTEOPOROSIS (mostly teriparatide)	$6.2
WBC STIMULANTS	$5.1
ANTISERA (e.g., Hizentra)	$4.8
ADHD –WAKEFULNESS – sodium oxybate [Xyrem]	$4.6
IMMUNOSUPPRESSIVES	$4.4
FSH-LH FERTILITY	$3.9
RBC STIMULANTS	$3.8

Top 20 = 93% of total

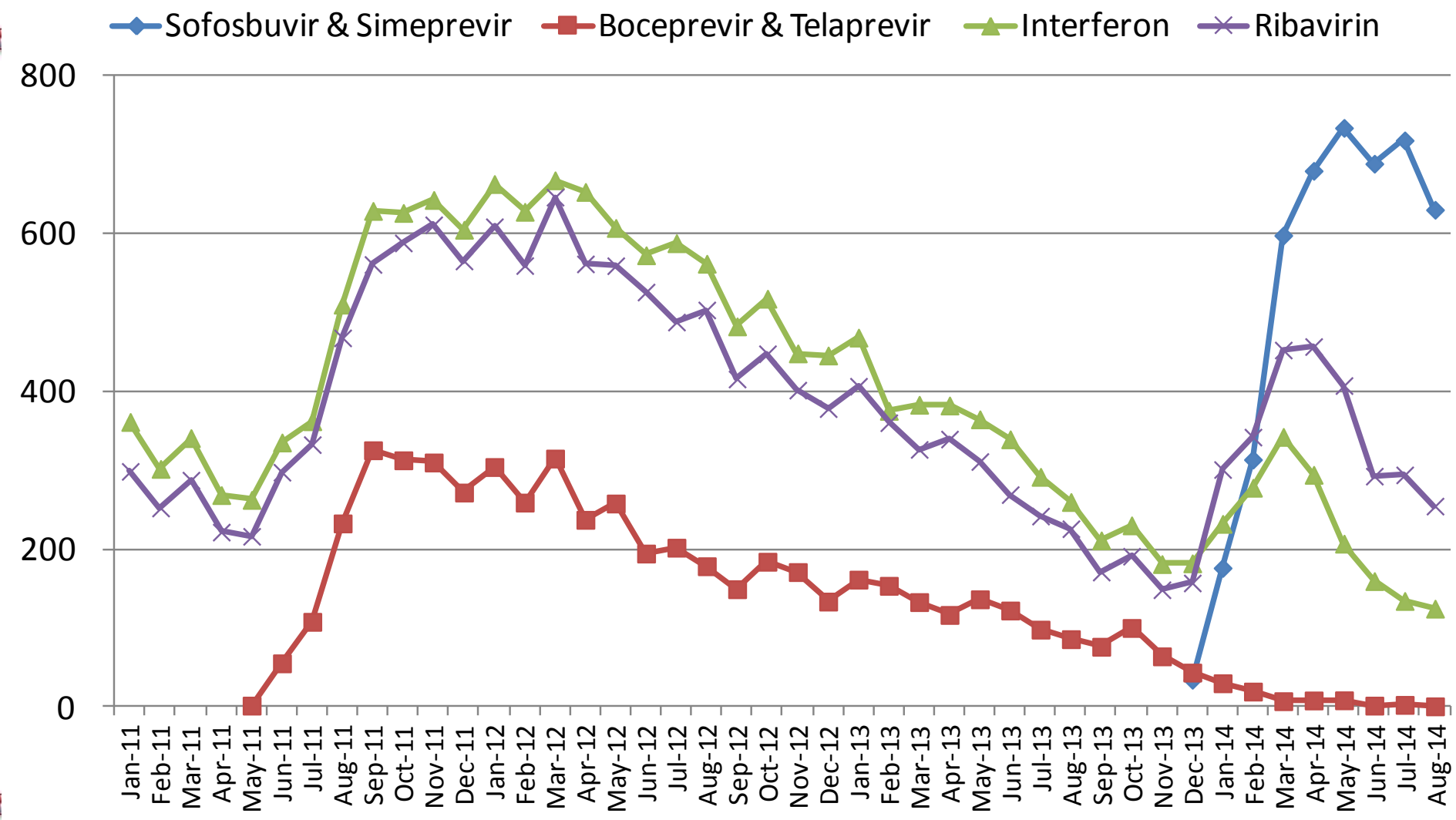
Refund-adjusted (at NDC level); omits paper claims, compounds, COB claims, OTC; based on 2QFY14 Specialty Agent Reporting List

Specialty Medications
Takeaways

- Spending on specialty medication has experienced significant growth and trend is expected to continue
- Multiple planned formulary management evaluations from DoD P&T Committee for specialty medication
  - TIBs (Aug 2014); PAH and MS (Nov 2014)
  - Oncology Agents (Feb 2015); HCV (May 2015)
- Evaluate cost effectiveness at the site of care for specialty medication (MTF/mail order vs. retail)
- Ensure safe and effective use of specialty medication for all MHS beneficiaries

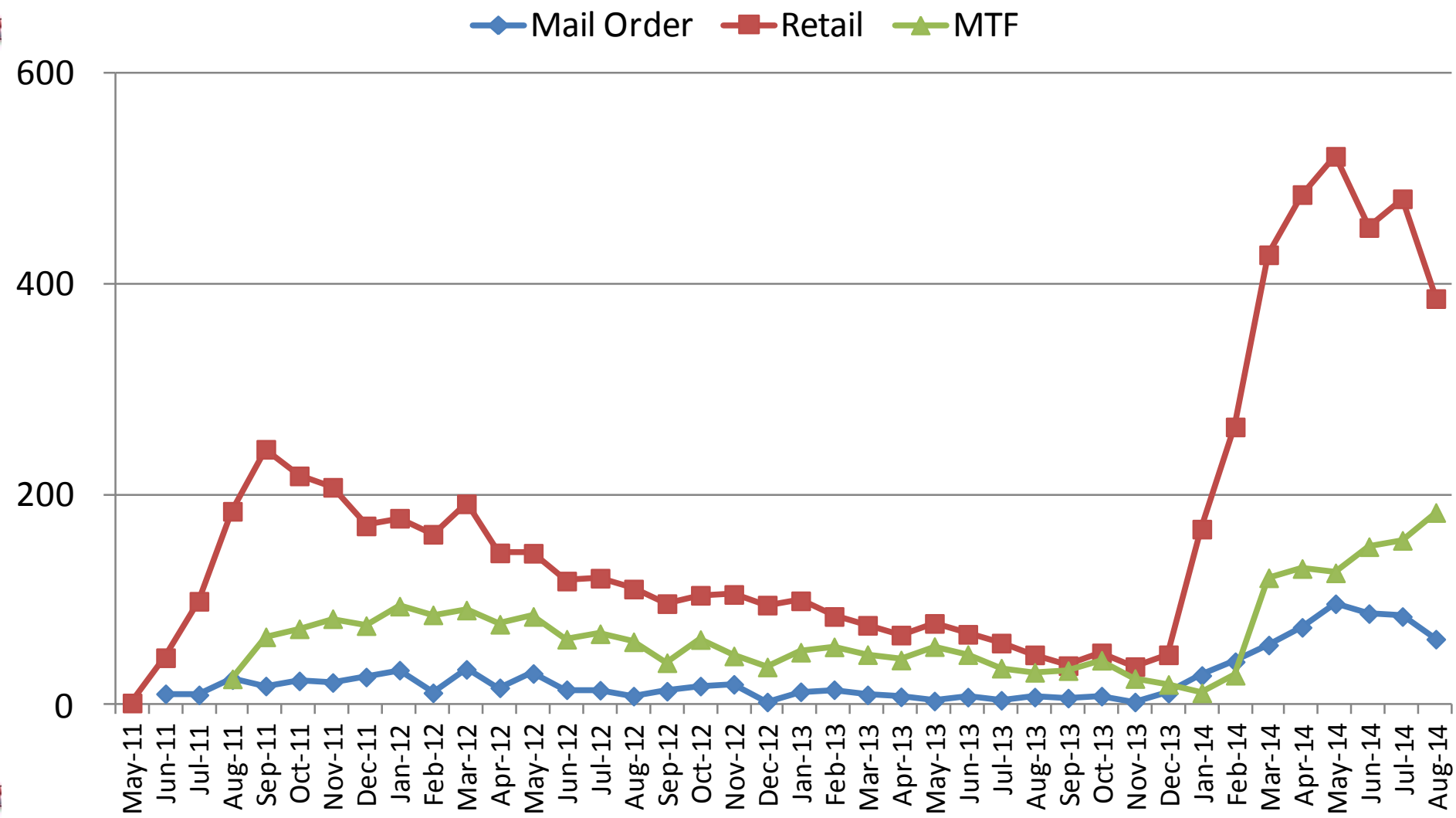
Hepatitis C

Hepatitis C Agents
30 DE – Direct Acting, INF, and RBV



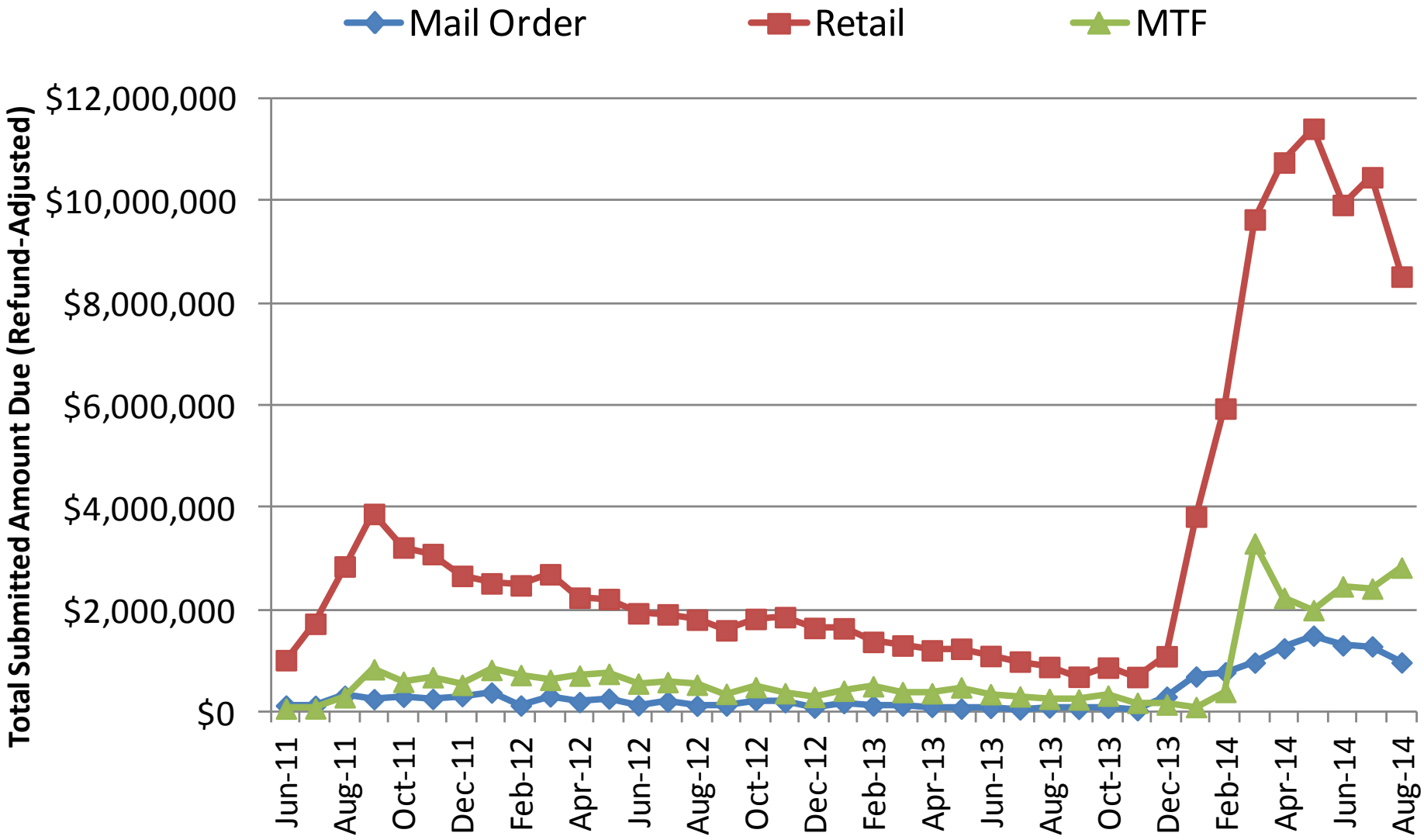
Source: PDTS

Hepatitis C Agents
30 DE – Direct Acting Agents by POS



Source: PDTS

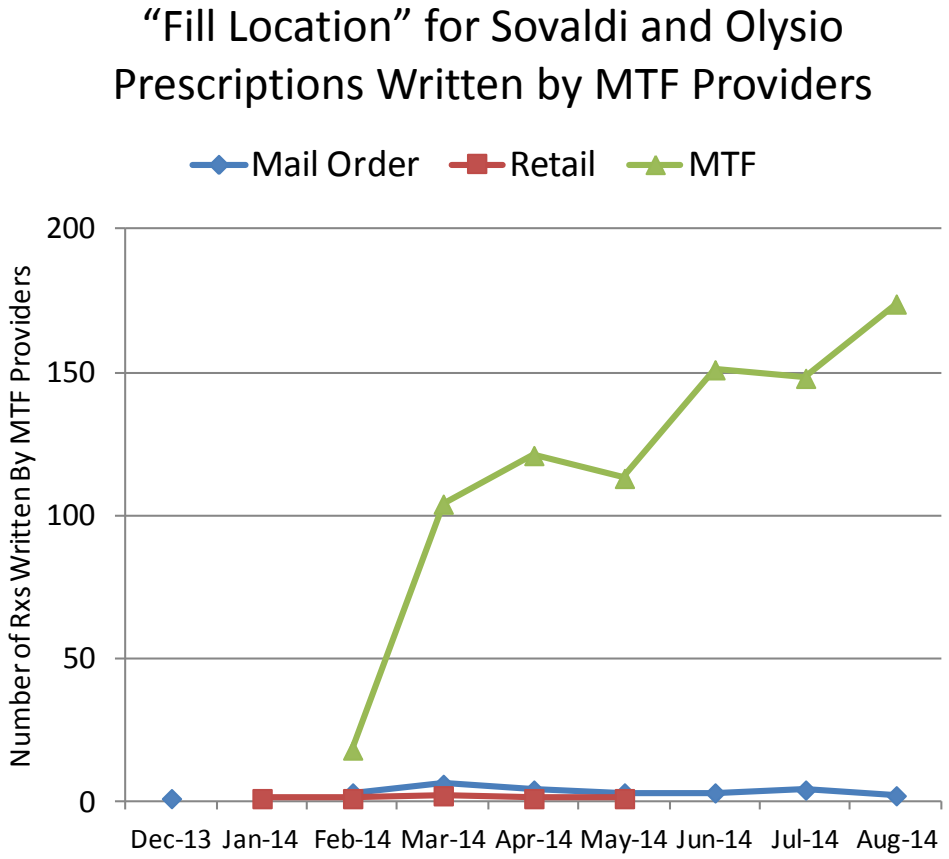
Hepatitis C Agents
Cost – Direct Acting, INF, and RBV



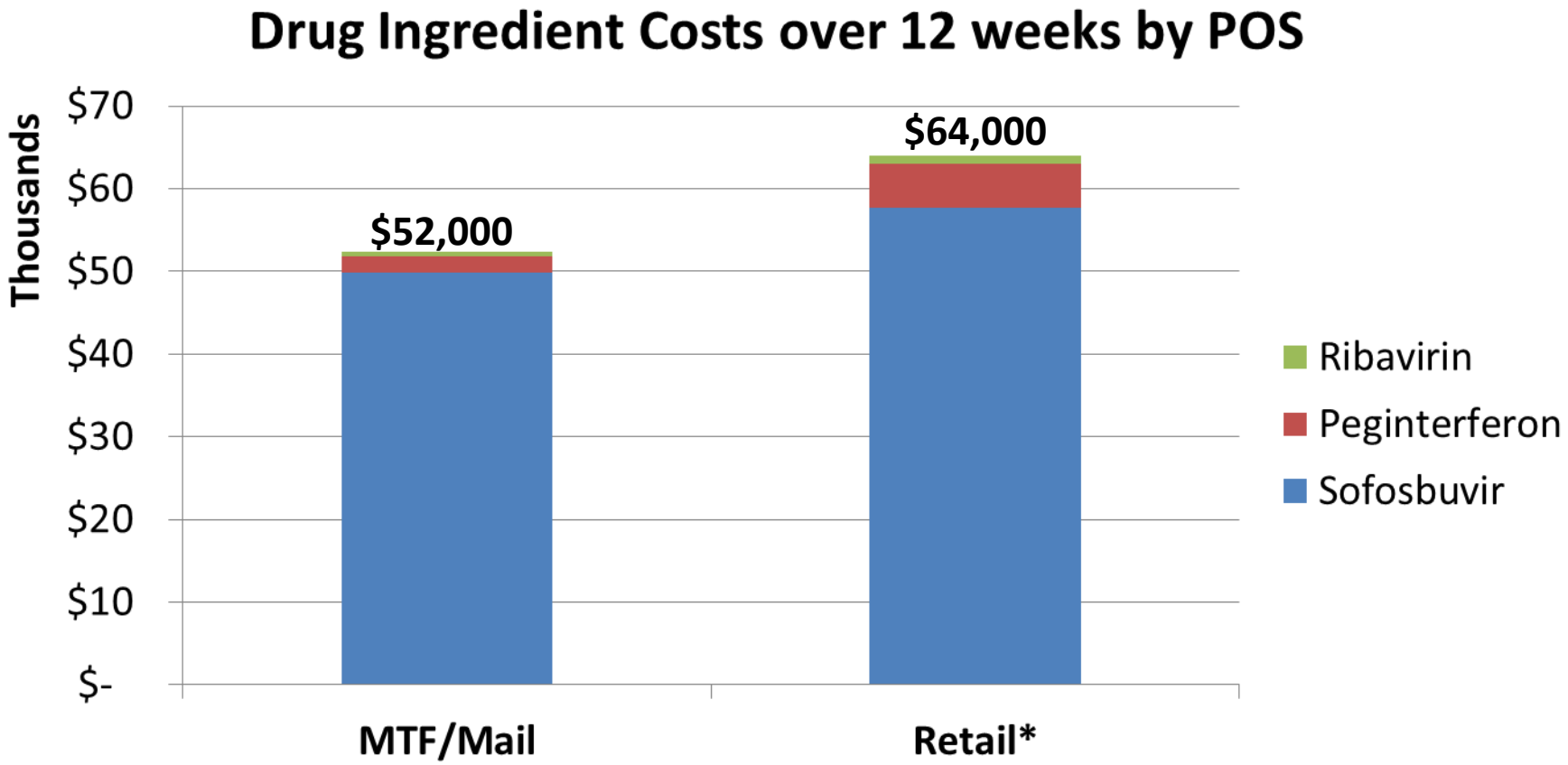
Source: PDTS

Hepatitis C Agents
MTF Provider Prescriptions

- Majority (96%) of Sovaldi and Olysio prescriptions written by MTF providers were filled in MTF pharmacies
- Significant savings are realized when these medications filled in the direct care system (MTF/Mail vs Retail)



Estimated Cost of HCV (Genotype 1) Treatment by Point of Service (POS)



* Retail total cost after refunds for sofosbuvir and PEG-IFN

HCV Takeaways

- About 1255 MHS patients have been treated to date (Aug 2014) with either sofosbuvir (Sovaldi) or simeprevir (Olysio) or both
- Vast majority of MTFs executing “write it, fill it”
- Opportunity for HCV recapture at MTFs
- Use PEC website for PA resources to assist with MTF formulary management
- Recommend against additional end of year purchases for Hep C agents pending availability of new interferon-free oral regimens in near future

Polling Question

Do you have sufficient funding in the pharmacy budget to fill Sovaldi Rxs from outside specialists?

A. Yes

B. No

Telmisartan Update

Average Cost of Selected Angiotensin Receptor Blockers (ARBs)

Defense Health Agency

Methodology:

- Pulled MTF prime vendor purchases of ARBs from Apr – Jun 14
- Applied August 2014 pricing updates provided by DLA

Results:

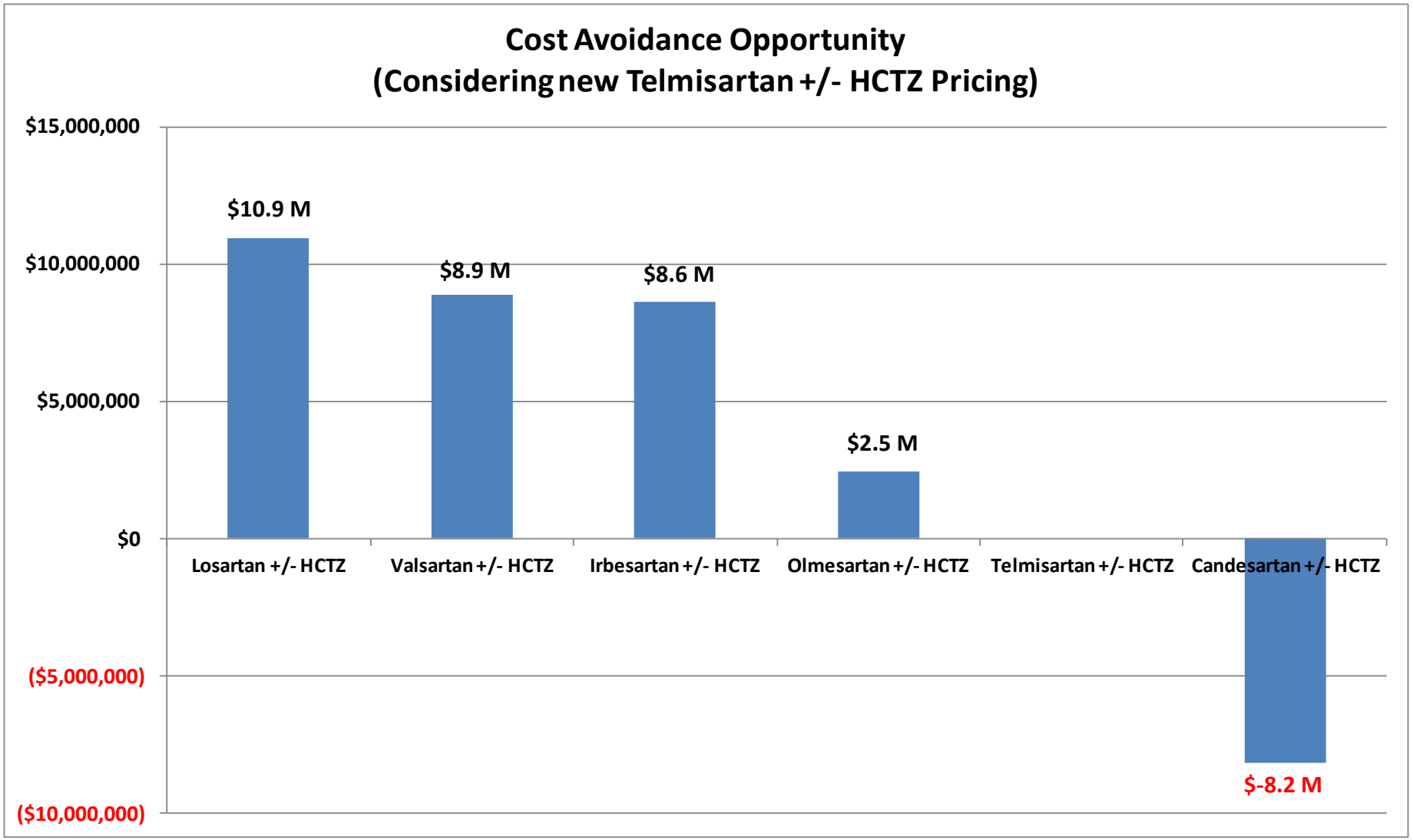
Medications	MTF Tabs Delivered (PV)	Average Unit Cost	Difference in Unit Costs
Losartan +/- HCTZ	8,339,280	$0.10	$1.32
Valsartan +/- HCTZ	2,205,060	$0.34	$1.07
Irbesartan +/- HCTZ	113,190	$0.38	$1.04
Olmesartan +/- HCTZ	126,570	$1.12	$0.30
Telmisartan +/- HCTZ	8,301,030	$1.42	-
Candesartan +/- HCT	813,720	$2.40	($0.99)

Temporary Price Reduction (TPR): 9/1/2014 12/31/2014
Will monitor for future TPRs/price changes after 2014

Conclusion:

- Telmisartan +/- HCTZ moved from being the most expensive ARB ($2.58/tab) to the second most expensive ARB ($1.42/tab) with their new TPR. Significant cost avoidance opportunities still exist.

Potential MTF Cost-Avoidance Opportunity with ARBs per Quarter



Telmisartan Take Home Bullets

- Many choices among ARBs; agents are fairly interchangeable
- Losartan and Valsartan remain Basic Core Formulary (BCF)
- Telmisartan moved from BCF to Uniform Formulary (UF)
  - Currently has ~ 50% of MTF market share by volume
- Opportunity to switch to more cost-effective medications in class

- Way forward:
  - At a minimum, brief local providers on price differences in class
  - Local P&T committee can discuss and recommend switching campaigns, if they deem appropriate
  - DOD P&T committee (or subgroup of clinicians) can address and make recommendations to field

Polling Question

Based on the information presented do you plan on implementing a switch in ARBs?

A. Yes

B. No

Compounding Update

- GAO Report will be published end of September
  - Likely to focus on disparity of Regulations (i.e. FDA approved) and current patient care needs (i.e. paying for compound prescriptions)
- Providing input for ASD/HA response to GAO
  - Analysis of options to ensure safety / cost control / appropriate therapy for compounded prescriptions
  - Considering options that may be created by NDAA 15 and pending actions from FDA
- Recommend you understanding your MTF activity
  - Compound Rx Demand; In-house compounding; Other sources

Questions

- **Questions?**
- **For additional information, please reach out to one of the following:**
  - DHA Pharmacy Operations Division Chief: Dr. George Jones, george.e.jones@dha.mil
  - Air Force Pharmacy Consultant: Col Scott Sprenger, scott.a.sprenger.mil@mail.mil
  - Army Pharmacy Consultant: COL John Spain, john.spain1@us.army.mil
  - Navy Pharmacy Consultant: CAPT Thinh Ha, thinh.ha@med.navy.mil

Backup

21 CFR 1308.13(e)(1) (iii) and (iv)

- Narcotic Drugs. Unless specifically excepted or unless listed in another schedule:
  - (1) Any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:
    - (iii) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium
    - (iv) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts