

# Training the New Disclosure / Aggregate Spend Workforce



Fresenius Medical Care

**Patrick M. Mooty, J.D.**

Senior Director,  
Ethics and Compliance  
Renal Products Division  
Renal Pharmaceuticals  
FMC Canada

**Fresenius Medical Care  
North America**  
920 Winter Street  
Waltham, MA 02451-1547

Direct: 781-699-9131  
Main: 800-662-1237 Ext. 9131  
Fax: 781-372-9585  
Patrick.Mooty@fmc-na.com

The views of the Fresenius presenter are those of the presenter,  
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# Our Agenda

- Why Train?
- Getting Ducks in a Row
- Shared Responsibility
- Communicating and Tailoring Training Material
- One Size Does Not Fit All
- Training Examples That Have Resonated



## Why Do We Need To Train Our Employees About Aggregate Spend?

- To live up to our Core Values
- It's the law
- It's a critical element of an effective compliance program
- To protect our companies and our brands
- To educate and empower our employees
- Compiling and reporting accurate data requires processes, resources and training

## Why Do We Need To Train Our Employees About Aggregate Spend?

Let's hear from our regulators:

“We need to ensure a smooth plan toward increasing disclosure, eliminating conflicts, and ultimately providing patients with the tools they need to make informed health choices.”

Letter dated November 4, 2010, from U.S. Senators Kohl + Grassley to HHS Secretary Sebelius, imploring the Secretary to expedite the implementation of the Physician Payment Sunshine provisions

# Training: Getting Your Ducks in a Row



Identify team that will drive aggregate spend compliance within the company

Attain thorough understanding of laws, regulations, and tracking and reporting requirements

Complete a risk assessment that encompasses aggregate spend issues

Develop and issue policies, procedures, and processes designed to ensure compliance with tracking + reporting requirements

Develop + deliver **TRAINING** to colleagues to provide clear communication of requirements, processes and expectations

# Accurate + Complete Reporting Is a Shared Responsibility of All Employees

**Ethics & Compliance Officer**



**Sales**

**Marketing**

**Medical Affairs**

**R&D**

**Managed Markets**

**HR**

**Finance**

**Gov't Affairs**

**Manufacturing**

**Customer Service**

**Technical Services**

## Accurate + Complete Reporting Is a Shared Responsibility of All Employees

- Training not limited to employees who interact with HCPs
  - Support operations, Finance, administrative staff, third party vendors
- Product Launch / Task Force concept
- Tone at the top is critical
- Office of Ethics and Compliance as engine, facilitator + synthesizer
- Collaborative efforts + common goals
- ***INTERCONNECTEDNESS***: If any member of the team provides inaccurate or incomplete data, the entire process has been compromised

## Content of Training

- ***NOT ONLY*** state and federal laws, regulations and forms . . .
- . . . ***BUT ALSO*** internal policies, processes and systems designed to track expenditures and comply with the rules
- Identify expenses that must be tracked
- Mastery of internal tracking systems
- Identify errors / inaccuracies / gaps in system and raise issues to AggSpend Task Force



## Content of Training

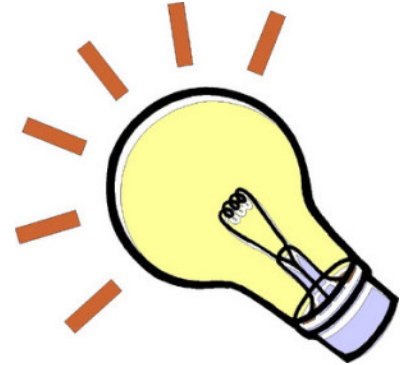
- Sufficient knowledge of vendor systems to request or extract required data and identify inaccurate or incomplete information
- ***INTERCONNECTEDNESS***: Require employees to certify that data submitted to Finance / Compliance are accurate and complete.



## Our Responsibility To Communicate Aggregate Spend Training Messages

Training our colleagues requires us to:

- **CC: Concretize Concepts**
- Teach them about the rules
- Answer questions clearly, even when the questions ask about the “gray area”
- Explain why
- Prepare them for new developments
- Manage expectations (***TRANSPARENCY***)



## Our Responsibility To Communicate Aggregate Spend Training Messages

Be prepared to answer detailed questions:

- An SVP attending a national conference in Seattle has a business lunch with her counterpart at ABC Company (an acquisition target). Must we report that expense if the ABC employee is not an HCP? . . . a Maine HCP? . . . a New Mexico HCP?
- How do we document no shows?

## Our Responsibility To Communicate Aggregate Spend Training Messages

Be prepared to answer detailed questions:

- Are Patient Care Technicians, Anemia Managers, and Registered Dietitians considered “Health Care Practitioners?”

### MAINE EXAMPLE

- “The Department will treat Food to an office or office staff as food to the prescriber, clinic or facility. If the food is a sixty dollars (\$60) luncheon for an office of three physicians and three non-prescribing office staff, the food amount shall be attributed in whole to the clinic or facility and is reportable.”<sup>1</sup>
  - So we report by *clinic*, rather than *recipient*?

<sup>1</sup>. *Maine Center for Disease Control and Prevention, Maine PDMC Record Layout Spreadsheet (Values tabbed worksheet), available at [http://www.maine.gov/dhhs/boh/documents/clinical\\_trials/Marketing\\_Report\\_Layout.xlsam](http://www.maine.gov/dhhs/boh/documents/clinical_trials/Marketing_Report_Layout.xlsam) (last visited Feb. 15, 2011).*

# Tailoring Training Efforts to the Level and Function of the Employee

One size does *not* fit all.

## ***SALES***

Tracking has become a part of everyday routine

- Live training
- Case studies
- Q&A sessions
- Refresher training
- Tracking system w/ FAQs + manuals

## ***EXECUTIVE LEADERSHIP***

Awareness of prohibitions, limits and data required to be tracked

- Live training
- WebEx
- Q&A sessions

## ***ADMINISTRATIVE SUPPORT***

Deep understanding of nuts + bolts of internal policies, processes and systems that track spend

- Live training
- Intense review of policies + instruction manuals
- Q&A sessions

# Tailoring Training Efforts to the Level and Function of the Employee

One size does *not* fit all.

<b><i>SALES</i></b>	Sales reps must have a comprehensive knowledge of the laws that govern their promotional and marketing activities. They must also master the information systems that track aggregate spend to ensure accurate reporting.
<b><i>EXECUTIVE LEADERSHIP</i></b>	Executive leaders may or may not interact with HCPs frequently. If they become educated about marketing disclosure laws and trends, they may allocate budget + resources to accelerate compliance efforts.
<b><i>ADMINISTRATIVE SUPPORT</i></b>	Administrative support staff must have an accurate command of the expenses of the manager(s) whom they support. They must also master the information systems that track aggregate spend to ensure accurate reporting.

## Special Considerations for Sessions with the Executive Leadership Team

- Describe the scope of resources needed to comply with enacted and anticipated requirements
- Seek budget funding for initiatives
- Present job descriptions: Aggregate Spend Manager, *etc.*
- Request support for Product Launch / Task Force-level commitment to AggSpend projects

## Integrating Aggregate Spend Training into Existing Training Process

- **GOAL:** Continuous communication of expectations + reinforcement of behaviors
- Develop a matrix of roles to identify employees who will require the training
- New hire orientation
- General Compliance Training and / or Functional Compliance Training
- New manager training
- Live training at launch meetings, quarterly updates, annual summits, national conferences
- Booth training prior to national conferences



## Integrating Aggregate Spend Training into Existing Training Process

- Refresher training
- DOS calls
- Training workshops
- Compliance Corner e-newsletter
- Intranet postings
- Updates related to enactment of new legislation



- Office hours

## Implementing Strategies To Validate Training and for Management To Hold Personnel Accountable

- Add Aggregate Spend Training metrics to Compliance Scorecard
- Lobby executive leadership to include Aggregate Spend Training metrics to Key Performance Indicators
- Add Aggregate Spend Training component to annual performance review
- Link incentive bonuses to Aggregate Spend Training metrics
- Audit training records to verify satisfactory + timely completion of Aggregate Spend Training courses
- Present scorecards / metrics at Corporate Compliance Committee meetings

# Managing Expectations: AMSA PharmFree

"The AMSA PharmFree Scorecard evaluates conflict-of-interest policies at 152 medical colleges . . . with a focus on interaction between students or faculty and the pharmaceutical industry."

"The Scorecard examines potential conflicts of interest created by industry marketing at the level of the individual physician and trainee."

**amsa** AMERICAN MEDICAL STUDENT ASSOCIATION  
**AMSA PharmFree Scorecard 2010**

**Conflict of Interest Policies at Academic Medical Centers**

SHOWING: All in DC **SHOW ALL** SEARCH: State **DC** City  **GO!**

Click on any school to learn more.  To sort by domain score, please use arrows. **BETTER**   **WORSE**

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<input type="checkbox"/> Howard University College of Medicine Washington, DC	<b>F</b>	○	○	○	○	○	○	○	○	○	○	○	This institution has ... <a href="#">Learn More</a>

What the results mean...

- Model policy
- Good progress toward model policy
- No policy, or policy unlikely to have a substantial effect on behavior
- Did not report
- NA Policy not relevant to this institution (e.g., does not make purchasing decisions)

AMSA PharmFree Scorecard 2010. *Conflict of Interest Policies at Academic Medical Centers* (online), <http://www.amsascorecard.org/>, Reston, VA: American Medical Student Association (last visited Feb. 15, 2011).

# Managing Expectations: Vendormate

- Vendormate is a healthcare vendor management solution that enables its clients to meet **TRANSPARENCY + COMPLIANCE** goals
- An entity like a hospital or ambulatory surgical center outsources its credentialing responsibilities to Vendormate
- Vendormate may, for example, restrict access to a hospital client to those pharmaceutical + medical device sales reps who have completed a thorough credentialing process agreed upon by Vendormate + the hospital
- Ethics and Compliance learned that several reps were having Vendormate issues with longtime customers
- **VALUE ADD:** Sales, HR and Ethics and Compliance worked together to create a policy, process and a template portfolio of documentation so that each rep would only need to click “SEND” in order to maintain continuity with contacts at hospitals that had transitioned to Vendormate

# Teaching About Transparency: 1 Tall White Chocolate Mocha To Go

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## Pharmaceutical companies spending less on Minnesota doctors

The economy played a role, but so, perhaps, did greater scrutiny  
By [Jeremy Olson](#)  
[olson@pioneerpress.com](mailto:olson@pioneerpress.com)  
Updated: 07/06/2009 10:46:18 AM CDT

Minnesota doctors received millions of dollars less from pharmaceutical companies in 2008 for research, lectures and consulting than they did in each of the five previous years, according to a Pioneer Press analysis of newly released state data.

A convergence of several pressures may have reduced the drug company spending, which, depending on whom you ask, either drives pharmaceutical innovation or buys off doctors so they'll prescribe more brand-name medications.

Clinic groups tightened rules on when doctors can accept industry funding. A few even outlawed company-sponsored luncheons, speeches and gifts. The bad economy also might have reduced drug-company spending on marketing and lecture sponsorships.

A key question is whether more public scrutiny of these payments had any effect.

The Minnesota Board of Pharmacy has collected this information for 15 years but the paper records received little

**Related content**

- Search to see if your doctor received money from drug companies

Jeremy Olson, *Pharmaceutical Companies Spending Less on Minnesota Doctors*, available at [http://www.twincities.com/ci\\_12573822?IADID=Search-www.twincities.com-www.twincities.com](http://www.twincities.com/ci_12573822?IADID=Search-www.twincities.com-www.twincities.com) (last visited Feb. 15, 2011).

# Teaching About Transparency: 1 Tall White Chocolate Mocha To Go

http://extra.twincities.com/car/doctors/docdetail.asp?Doctor=SMITH;CHARLES^MINNEAPOLIS

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MY YAHOO!

Your search returned the following records of payments to **CHARLES SMITH**. Start a [new search](#).

Doctor Name	Practice Name	City	Paying Company	Payment Year	Description	Amount
SMITH, CHARLES		MINNEAPOLIS	ELI LILLY	2005	REIMBURSEMENT, HONORARIA OR CONSULTING SERVICES	\$4,039.80
SMITH, CHARLES		MINNEAPOLIS	ORTHO BIOTECH	2005	CONSULTING FEE AND EXPENSES IN RELATION TO SPEAKING ENGAGEMENT	\$500.00
SMITH, CHARLES		MINNEAPOLIS	AMGEN USA	2007	Promotional Speaker Program Expenses	\$16.00
SMITH, CHARLES		MINNEAPOLIS	AMGEN USA	2007	Promotional Speaker Program Expenses	\$45.00
SMITH, CHARLES		MINNEAPOLIS	AMGEN USA	2007	Promotional Speaker Program Expenses	\$26.00
SMITH, CHARLES		MINNEAPOLIS	AMGEN USA	2007	Promotional Speaker Program Expenses	\$4.00
SMITH, CHARLES		MINNEAPOLIS	AMGEN USA	2007	Promotional Speaker Program Expenses	\$27.72
SMITH, CHARLES		MINNEAPOLIS	AMGEN USA	2007	Promotional Speaker Program Expenses	\$73.00

*Payments to Minnesota Doctors and Other Caregivers, available at*  
<http://extra.twincities.com/car/doctors/docdetail.asp?Doctor=SMITH;CHARLES^MINNEAPOLIS>  
 (last visited Feb. 15, 2011).

## Teaching About Transparency: Shopping Carts

SMDC Health System (now a member of Essentia Health) is a healthcare provider that operates 4 hospitals + 17 clinics in Minnesota + Wisconsin.

In Q1 2008 SMDC elected to remove all the promotional items that pharmaceutical companies had provided to SMDC hospital + clinic employees.

It took       ? shopping carts to corral the materials.







## Teaching About Transparency: Shopping Carts

### POINT

“‘We’re part of a leading trend that’s trying to get away from the pharmaceutical companies essentially controlling what’s prescribed in this country,’ said Dr. Kenneth Irons, chief of community clinics for SMDC. ‘This shows people we’re not in the pharmaceutical companies’ pockets.’”<sup>1</sup>

### COUNTERPOINT

“‘I’ve never seen nor heard of a systematic roundup of pens and coffee mugs before . . . It’s a bit draconian. But the onus is on us now to do a better job of explaining the job and the importance of marketing representatives. Unfortunately there are a lot of cynics in America who want to think the worst.’”<sup>2</sup>

1. Larry Oakes, *Duluth-Based Health System Bans Pharmaceutical Logos*, available at <http://www.startribune.com/templates/fdcp?1292854973332> (last visited Feb. 15, 2011).
2. Associated Press, *Minn. Hospitals, Clinics Purge Drug Co. Trinkets*, available at <http://www.msnbc.com/cleanprint/CleanPrintProxy.aspx?1292854339781> (last visited Feb. 15, 2011).

## Aggregate Spend Training: Defining Success

- **CCC: Clear Communication to Colleagues**
- Playing by the rules
- Accurate results + timely reporting
- Team approach
- Understanding of roles + responsibilities
- Discussion + resolution of “gray area” issues
- Learning from missteps
- Process improvements
- Updated policies, procedures + training

# What Am I Certifying?

I am certifying that our team “gets it,” that we have been trained appropriately, and that our submissions are accurate + complete.

Vermont Office of the Attorney General  
109 State Street  
Montpelier, VT 05609-1001

FY10 Compliance Officer Form - Due Date: July 1, 2010

## Section V: Declaration

*I certify that the information stated by me in this disclosure is true and accurate to the best of my knowledge.*

*I understand that providing false information or omission of information is unlawful.*

Certify by typing name	Submission Date
Patrick Mooty	6/29/2010

Vermont requires electronic filing, print this form for your records

Print

Submit

If filing disclosures for FY10, please send a check made out to "State of Vermont" for \$500 by July 1, 2010 to:

Massachusetts Department of Public Health Online Licensing System - Microsoft Internet Explorer

Address: <https://elic-web-test-1.hhs.state.ma.us/MyLicense%20Enterprise/Summary.aspx>

### Attestation

MY SIGNATURE ON THIS RENEWAL APPLICATION ATTESTS THAT TO THE BEST OF MY KNOWLEDGE AND BELIEF, I HAVE COMPLIED WITH:

- PURSUANT TO MGL C.62C, S.49A TO MY BEST KNOWLEDGE AND BELIEF, I HAVE FILED ALL STATE TAX RETURNS AND PAID ALL STATE TAXES REQUIRED BY LAW.
- I AM LEGALLY AUTHORIZED BY THE LICENSED ENTITY TO COMPLETE AND SUBMIT THIS APPLICATION.
- OUR COMPANY HAS A MARKETING CODE OF CONDUCT IN COMPLIANCE WITH 105 C.M.R. 970.000.
- OUR COMPANY HAS ADOPTED A PROGRAM TO ROUTINELY TRAIN APPROPRIATE EMPLOYEES, INCLUDING, WITHOUT LIMITATION, ALL SALES AND MARKETING STAFF REGARDING THE MARKETING CODE OF CONDUCT, AS DESCRIBED IN 105 C.M.R. 970.000. A COPY OF THE TRAINING PROGRAM IS AVAILABLE TO THE DEPARTMENT OF PUBLIC HEALTH ON REQUEST (DO NOT SEND COPIES).

Vermont Office of the Attorney General, *FY10 Compliance Officer Form*, available at <http://www.atg.state.vt.us/assets/files/FY10%20Compliance%20Officer%20Form.pdf> (last visited Feb. 15, 2011).

Massachusetts Executive Office of Health and Human Services, *Pharmaceutical Code of Conduct Manufacturer Registration Renewal Manual*, available at [http://www.mass.gov?Eeohhs2/docs/dph/quality/healthcare/pharm\\_manufacturers\\_license\\_renewal.pdf](http://www.mass.gov?Eeohhs2/docs/dph/quality/healthcare/pharm_manufacturers_license_renewal.pdf) (last visited Feb. 15, 2011).

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- **Thank you!**
  - **If you are from New England and are interested in joining the (informal) New England Compliance Forum, please introduce yourself or e-mail me: [patrick.mooty@fmc-na.com](mailto:patrick.mooty@fmc-na.com)**