

Memo

To: Manufacturers of Prescribed Products

From: Wendy Morgan, Chief of the Public Protection Division
Kate Whelley McCabe, Assistant Attorney General
Vermont Office of the Attorney General

Date: September 1, 2011

Subject: Examples of Disclosures for Sample and Over the Counter Product Distribution

As indicated at the time of the publication of the Guide to Vermont's Prescribed Product Gift Ban and Disclosure Law for 2011 Disclosures, the Office has put together some sample disclosure forms for reporting the distribution of samples and allowable expenditures related to the distribution of reasonable amounts of over the counter products. The descriptions below correspond to the sample completed forms.

[Example A: Drug Sample – Prescribed Product](#)

On January 10, 2011, ACME 123 Company distributed 2 samples of XYZ pill to Dr. John Q. Doe. Each sample consisted of a bottle of pills containing 50, 200 milligram pills.

[Example B: Drug Sample – Voucher](#)

On January 10, 2011, ACME 456 Company distributed a book of 25 vouchers to APRN Janice Q. Doe. Each voucher allowed for up to \$50 savings on a prescription and two refills of pharmaceutical DEF in any of three strengths each of the aerosol or powder formulations of the product.

[Example C: Drug Sample – Voucher – Multiple Manufacturers](#)

Manufacturers X Co., Y Co., and Z Co. have partnered to offer a voucher good for 25% off of certain of their prescription drugs. With respect to Manufacturer X's products, the voucher is good for 25% off of a single prescription of Manufacturer X Co.'s A, B, and C pills. On January 10, 2011, Manufacturers X Co., Y Co., and Z Co. distributed 50 of these vouchers to Dr. Jaye Q. Doe. Manufacturer X is reporting.

[Example D: Drug Sample – Starter Pack with Prescribed Product. Literature and Non-Prescribed \(Over the Counter\) Item](#)

On January 10, 2011, QRS Company distributed 10 starter packs of HIJ pill to APRN James Q. Doe. Each starter pack contained 1 blister pack of 14, 100 milligram pills, an FDA label, a

medication guide, and 1 tube TUV medicated lotion (a non-prescribed product) for treating dry skin associated with taking Pill HIJ.

Example E: Drug Sample – Starter Pack with Prescribed Product, Co-Pay Card and Literature

On January 10, 2011, RST LNE Company distributed 5 starter packs of NOP pill to Dr. Janelle Q. Doe. Each starter pack contained 1 bottle of 25, 50 milligram pills, 1 co-pay card allowing for up to \$20 off 6 prescriptions of a minimum, 30-day supply of NOP, a booklet entitled “Getting Started with NOP” and an FDA label.

Example F: Medical Device Sample – Starter Pack with Prescribed Product, Literature, and Other Items

On January 10, 2011, WXY Company distributed 5 starter packs to Dr. Jeremy Q. Doe. Each pack contained a JKL blood glucose meter, a package of 10 JKL blood glucose test strips, and a JKL lancing device. Each pack also contained a carrying case, a log book for recording blood glucose levels, and an owner’s booklet and other printed materials about the products in the starter pack.

Please note that non-prescription like items, such as educational materials, can be grouped together, i.e., as “owner’s booklet and other printed materials.”

If there are more than three prescribed products, vouchers, etc., or other items associated with a single sample, all of the information will not all fit on the disclosure form. Such disclosures should be made through the database rather than the form.

Example G: Biologic Sample – Prescribed Product

On January 10, 2011, KLMN Incorporated distributed 10 samples of RST vaccine to APRN Judith Q. Doe. Each sample included 1 vial of .5 milliliter RST hepatitis B immune globulin (HBIG) vaccine.

Example H: Expenditures Related to Distribution of Reasonable Quantity of Over the Counter (Non-Prescribed) Product

On July 1, 2011, ACME 789 Company distributed 5 packages of QRS Nicotine Gum to Dr. Jane Q. Doe for free distribution to patients. Each package contained 10 units of gum. In total, the gum had a value of \$15.

Please note that such expenditures should be disclosed with allowable expenditures and permitted gifts rather than as samples.

Example A: Drug Sample – Prescribed Product

On January 10, 2011, ACME 123 Company distributed 2 samples of XYZ pill to Dr. John Q. Doe. Each sample consisted of a bottle of pills containing 50, 200 milligram pills.

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

2011 Samples Disclosure Form for Manufacturers of Prescribed Products
Reporting Period: January 1, 2011 to December 31, 2011; Due Date: April 1, 2012

Name of Manufacturer		ACME 123 Co.		
Last Name of Recipient		Doe	First Name	John
Lic. Number/ID Number of Recipient		042-1234567		
Date Delivered		01/10/2011	Number of Samples	2
Contents (Check all that apply)		<input checked="" type="checkbox"/> Prescribed Product	<input type="checkbox"/> Vouchers, etc	<input type="checkbox"/> Other (Including Non-Prescribed Items or Educational Materials)
Prescribed Product				
Prescribed Product Type	Prescribed Product Name	Units/Sample	Dosage or N/A	Description
Pharmaceuticals	XYZ Pill	50	200 mg	bottles of pills, each containing 50 pills of 200 mg XYZ
Vouchers, Coupons, Co-Pay Cards, Etc.				
Prescribed Product Type	Prescribed Product Name or N/A	Vouchers/Sample	Description of Product/Discount	
Other (Including Non-Prescribed Items or Educational Materials)				
Prescribed Product Type	Prescribed Product Name or N/A	Other Sample Type	Description of Item/Discount/Material	

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Example B: Drug Sample – Voucher

On January 10, 2011, ACME 456 Company distributed a book of 25 vouchers to APRN Janice Q. Doe. Each voucher allowed for up to \$50 savings on a prescription and two refills of pharmaceutical DEF in any of three strengths each of the aerosol or powder formulations of the product.

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2011 Samples Disclosure Form for Manufacturers of Prescribed Products

Reporting Period: January 1, 2011 to December 31, 2011; Due Date: April 1, 2012

Name of Manufacturer		ACME 456 Co.			
Last Name of Recipient		Doe	First Name	Janice	MI Q
Lic. Number/ID Number of Recipient		101-1234567			
Date Delivered		01/10/2011	Number of Samples	25	
Contents (Check all that apply)		<input type="checkbox"/> Prescribed Product	<input checked="" type="checkbox"/> Vouchers, etc	<input type="checkbox"/> Other (Including Non-Prescribed Items or Educational Materials)	
Prescribed Product					
Prescribed Product Type	Prescribed Product Name	Units/Sample	Dosage or N/A	Description	
▼					
▼					
▼					
Vouchers, Coupons, Co-Pay Cards, Etc.					
Prescribed Product Type	Prescribed Product Name or N/A	Vouchers/Sample	Description of Product/Discount		
Pharmaceuticals ▼	DEF	1	up to \$50 off product + 2 refills for 3 strengths each, aerosol or powder		
▼					
▼					
Other (Including Non-Prescribed Items or Educational Materials)					
Prescribed Product Type	Prescribed Product Name or N/A	Other Sample Type	Description of Item/Discount/Material		
▼		▼			
▼		▼			
▼		▼			

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Example C: Drug Sample – Voucher – Multiple Manufacturers

Manufacturers X Co., Y Co., and Z Co. have partnered to offer a voucher good for 25% off of certain of their prescription drugs. With respect to Manufacturer X’s products, the voucher is good for 25% off of a single prescription of Manufacturer X Co.’s A, B, and C pills. On January 10, 2011, Manufacturers X Co., Y Co., and Z Co. distributed 50 of these vouchers to Dr. Jaye Q. Doe. Manufacturer X is reporting.

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2011 Samples Disclosure Form for Manufacturers of Prescribed Products

Reporting Period: January 1, 2011 to December 31, 2011; Due Date: April 1, 2012

Name of Manufacturer		X Co.		
Last Name of Recipient		Doe	First Name	Jaye
Lic. Number/ID Number of Recipient		042-9876543		
Date Delivered		01/10/2011	Number of Samples	50
Contents (Check all that apply)		<input type="checkbox"/> Prescribed Product	<input checked="" type="checkbox"/> Vouchers, etc	<input type="checkbox"/> Other (Including Non-Prescribed Items or Educational Materials)
Prescribed Product				
Prescribed Product Type	Prescribed Product Name	Units/Sample	Dosage or N/A	Description
Vouchers, Coupons, Co-Pay Cards, Etc.				
Prescribed Product Type	Prescribed Product Name or N/A	Vouchers/Sample	Description of Product/Discount	
Pharmaceuticals	multiple manufacturers	1	25% off 1 prescription of A, B or C pill; other manufacturers are Y Co., and Z Co.	
Other (Including Non-Prescribed Items or Educational Materials)				
Prescribed Product Type	Prescribed Product Name or N/A	Other Sample Type	Description of Item/Discount/Material	

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Example D: Drug Sample – Starter Pack with Prescribed Product. Literature and Non-Prescribed (Over the Counter) Item

On January 10, 2011, QRS Company distributed 10 starter packs of HIJ pill to APRN James Q. Doe. Each starter pack contained 1 blister pack of 14, 100 milligram pills, an FDA label, a medication guide, and 1 tube TUV medicated lotion (a non-prescribed product) for treating dry skin associated with taking Pill HIJ.

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2011 Samples Disclosure Form for Manufacturers of Prescribed Products
Reporting Period: January 1, 2011 to December 31, 2011; Due Date: April 1, 2012

Name of Manufacturer		QRS Co.			
Last Name of Recipient		Doe	First Name	James	MI Q
Lic. Number/ID Number of Recipient		101-2345678			
Date Delivered		01/10/2011	Number of Samples	10	
Contents (Check all that apply)		<input checked="" type="checkbox"/> Prescribed Product	<input type="checkbox"/> Vouchers, etc	<input checked="" type="checkbox"/> Other (Including Non-Prescribed Items or Educational Materials)	
Prescribed Product					
Prescribed Product Type	Prescribed Product Name	Units/Sample	Dosage or N/A	Description	
Pharmaceuticals	HIJ Pill	14	100 mg	starter packs, each w/ 1 blister pk. of 14, 100 mg pills	
Vouchers, Coupons, Co-Pay Cards, Etc.					
Prescribed Product Type	Prescribed Product Name or N/A	Vouchers/Sample	Description of Product/Discount		
Other (Including Non-Prescribed Items or Educational Materials)					
Prescribed Product Type	Prescribed Product Name or N/A	Other Sample Type	Description of Item/Discount/Material		
Pharmaceuticals	HIJ Pill	Educational Ma	FDA label		
Pharmaceuticals	HIJ Pill	Educational Ma	medication guide		
Pharmaceuticals	HIJ Pill	Non-Prescribed	1 tube TUV medicated lotion for treating dry skin associated with taking Pill HIJ		

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Example E: Drug Sample – Starter Pack with Prescribed Product, Co-Pay Card and Literature

On January 10, 2011, RST LNE Company distributed 5 starter packs of NOP pill to Dr. Janelle Q. Doe. Each starter pack contained 1 bottle of 25, 50 milligram pills, 1 co-pay card allowing for up to \$20 off 6 prescriptions of a minimum, 30-day supply of NOP, a booklet entitled “Getting Started with NOP” and an FDA label.

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2011 Samples Disclosure Form for Manufacturers of Prescribed Products
Reporting Period: January 1, 2011 to December 31, 2011; Due Date: April 1, 2012

Name of Manufacturer		RST LNE Co.			
Last Name of Recipient		Doe	First Name	Janelle	MI Q
Lic. Number/ID Number of Recipient		042-3456789			
Date Delivered		01/10/2011	Number of Samples	5	
Contents (Check all that apply)		<input checked="" type="checkbox"/> Prescribed Product	<input checked="" type="checkbox"/> Vouchers, etc	<input checked="" type="checkbox"/> Other (Including Non-Prescribed Items or Educational Materials)	
Prescribed Product					
Prescribed Product Type	Prescribed Product Name	Units/Sample	Dosage or N/A	Description	
Pharmaceuticals	NOP Pill	25	50 mg	starter packs, each with 1 bottle of 25, 50 mg pills	
Vouchers, Coupons, Co-Pay Cards, Etc.					
Prescribed Product Type	Prescribed Product Name or N/A	Vouchers/Sample	Description of Product/Discount		
Pharmaceuticals	NOP Pill	1	1 co-pay card good for up to \$20 off 6 prescriptions of min. 30-day supply of NOP		
Other (Including Non-Prescribed Items or Educational Materials)					
Prescribed Product Type	Prescribed Product Name or N/A	Other Sample Type	Description of Item/Discount/Material		
Pharmaceuticals	NOP Pill	Educational Ma	booklet: "Getting Started with NOP"		
Pharmaceuticals	NOP Pill	Educational Ma	FDA label		

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Example F: Medical Device Sample – Starter Pack with Prescribed Product, Literature, and Other Items

On January 10, 2011, WXY Company distributed 5 starter packs to Dr. Jeremy Q. Doe. Each pack contained a JKL blood glucose meter, a package of 10 JKL blood glucose test strips, and a JKL lancing device. Each pack also contained a carrying case, a log book for recording blood glucose levels, and an owner’s booklet and other printed materials about the products in the starter pack.

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2011 Samples Disclosure Form for Manufacturers of Prescribed Products
Reporting Period: January 1, 2011 to December 31, 2011; Due Date: April 1, 2012

Name of Manufacturer		WXY Co.			
Last Name of Recipient		Doe	First Name	Jeremy	MI Q
Lic. Number/ID Number of Recipient		042-8765432			
Date Delivered		01/10/2011	Number of Samples	5	
Contents (Check all that apply)		<input checked="" type="checkbox"/> Prescribed Product	<input type="checkbox"/> Vouchers, etc	<input checked="" type="checkbox"/> Other (including Non-Prescribed Items or Educational Materials)	
Prescribed Product					
Prescribed Product Type	Prescribed Product Name	Units/Sample	Dosage or N/A	Description	
Medical Devices	JKL Meter	1	N/A	starter pack, each with 1 blood glucose meter	
Medical Devices	JKL test strips	10	N/A	blood glucose test strips	
Medical Devices	JKL lancing device	1	N/A	blood glucose lancing device	
Vouchers, Coupons, Co-Pay Cards, Etc.					
Prescribed Product Type	Prescribed Product Name or N/A	Vouchers/Sample	Description of Product/Discount		
Other (including Non-Prescribed Items or Educational Materials)					
Prescribed Product Type	Prescribed Product Name or N/A	Other Sample Type	Description of Item/Discount/Material		
Medical Devices	multiple products	Other	carrying case for carrying JKL Meter, strips, lancing device		
Medical Devices	multiple products	Other	log book for recording glucose levels when using JKL Meter, strips, lancing device		
Medical Devices	multiple products	Educational Ma	owner's booklet and other printed materials re JKL Meter, strips, lancing device		

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Example G: Biologic Sample – Prescribed Product

On January 10, 2011, KLMN Incorporated distributed 10 samples of RST vaccine to APRN Judith Q. Doe. Each sample included 1 vial of .5 milliliter RST hepatitis B immune globulin (HBIG) vaccine.

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2011 Samples Disclosure Form for Manufacturers of Prescribed Products

Reporting Period: January 1, 2011 to December 31, 2011; Due Date: April 1, 2012

Name of Manufacturer		KLMN Inc.		
Last Name of Recipient		Doe	First Name	Judith MI Q
Lic. Number/ID Number of Recipient		101-3456789		
Date Delivered	01/10/2011	Number of Samples	10	
Contents (Check all that apply)		<input checked="" type="checkbox"/> Prescribed Product	<input type="checkbox"/> Vouchers, etc	<input type="checkbox"/> Other (Including Non-Prescribed Items or Educational Materials)
Prescribed Product				
Prescribed Product Type	Prescribed Product Name	Units/Sample	Dosage or N/A	Description
Biologics	RST Vaccine	1	.5 mL	vial of hepatitis B immune globulin (HBIG), each with .5 ml
Vouchers, Coupons, Co-Pay Cards, Etc.				
Prescribed Product Type	Prescribed Product Name or N/A	Vouchers/Sample	Description of Product/Discount	
Other (Including Non-Prescribed Items or Educational Materials)				
Prescribed Product Type	Prescribed Product Name or N/A	Other Sample Type	Description of Item/Discount/Material	

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Example H: Expenditures Related to Distribution of Reasonable Quantity of Over the Counter (Non-Prescribed) Product

On July 1, 2011, ACME 789 Company distributed 5 packages of QRS Nicotine Gum to Dr. Jane Q. Doe for free distribution to patients. Each package contained 10 units of gum. In total, the gum had a value of \$15.

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2011 Disclosure Form for Manufacturers of Prescribed Products

**Reporting Period for Pharmaceuticals, Biologics and Medical Devices
July 1, 2011 to December 31, 2011; Due Date: April 1, 2012**

You must disclose allowable expenditures and gifts which are not banned.

Name of Manufacturer	ACME 789 Co.		
Last Name of Recipient	Doe	First Name	Jane MI Q
Lic. Number/ID Number of Recipient	042-2345678		
Date Expenditure Incurred	07/01/2011		
Value/Amount of Expenditure	\$15.00		
Nature of Expenditure	Other	If "Other"	over the counter drug
Purpose of Expenditure	Other	If "Other"	free distribution to patients
FMV Payment Description	NA		
Prescribed Product(s) (up to five) to which expenditure or gift relates.			
Product Type	Over the Counter	Product Name	Nicotine Gum QRS; 5 packages, each with 10 units of gum
Product Type		Product Name	
Product Type		Product Name	
Product Type		Product Name	
Product Type		Product Name	

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