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CENTER FOR MEDICARE

TO: Part D Plan Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Enhancements to Medicare Part D Patient Safety Reports and Website

DATE: September 30, 2010

CMS is launching several new report enhancements on the Patient Safety Analysis Website that is available for Part D sponsors to access. These enhancements, which will be described in more detail, include:

- Reports updated with 2010 Prescription Drug Event (PDE) data,
- Updated National Drug Code (NDC) lists for the Drug-Drug Interaction (DDI) and the Diabetes Medication Dosage (DMD) measures,
- A new Adherence Measure report,
- An 'At-a-Glance' Rate Summary website feature,
- Performance graphs, and
- Outlier notifications.

To access the Patient Safety Reports and outlier notifications, you must be an authorized user of the Patient Safety Analysis Website. The access authorization process is described in this memo. The deadline for new user authorization is one week after the date of this memo.

Background

Performance and quality measures were developed by CMS so that Medicare beneficiaries have the information necessary to make informed enrollment decisions by comparing available health and prescription drug plans and to serve as a measure of drug plan performance. As part of this effort, CMS currently calculates and publicizes four patient safety measures: High Risk Medication (HRM), Drug-Drug Interaction (DDI), Diabetes Treatment, and Diabetes Medication Dosage (DMD). The HRM and Diabetes Treatment measures, which are adapted from the measures developed and endorsed by the Pharmacy Quality Alliance (PQA) and endorsed by the National Quality Forum (NQF), contribute to a plan's Part D Star Rating and are available on the Medicare Prescription Drug Plan Finder (MPDPF) at www.medicare.gov. The DDI and DMD measures, which are measure concepts developed and endorsed by the PQA, are part of the Display Measures available on the CMS website (<http://www.cms.hhs.gov>).

Part D sponsors currently have access to patient safety reports via the Patient Safety Analysis Website to compare their rates to overall averages and monitor their progress in improving patient safety measures over time. These reports, which contain actionable contract-level, provider-level, beneficiary-level and claim-level analyses, can be downloaded on a monthly basis from the Patient Safety Analysis website (<https://PartD.ProgramInfo.US/PatientSafety>). For additional information, report user guides and NDC level medication lists are available for each of the patient safety measure reports on the Patient Safety Website under Help Documents.

Patient Safety Reports and Website Enhancements

Reports updated with 2010 Prescription Drug Event (PDE) data

CMS will begin releasing monthly 2010 Patient Safety Reports. The measures in these reports are calculated with 2010 PDE data received up until one month before the release of the report. For example, the reports released on November 30, 2010 contain PDE data received from January 2010 through October 2010. Each monthly report is updated as more complete 2010 PDE data are received from Part D plans. The final 2010 Patient Safety Reports will be released in July 2011, one month after all 2010 PDE records must be submitted to CMS.

Updated NDC lists for DDI and DMD measures

The National Drug Code (NDC) lists for the DDI and DMD measures have been updated by the Pharmacy Quality Alliance (PQA), and CMS will immediately begin using these updated NDC lists to calculate the measures. Rates will be calculated using these updated NDC lists beginning with the next report release on the Patient Safety Analysis Website. The updated lists at the drug name level are provided in Attachment 1: Medication Lists.

New Adherence measure report

CMS is launching a new Part D Display Measure, the Adherence measure. The Adherence measure is adapted from the Proportion of Days Covered (PDC) measure which was developed and endorsed by the Pharmacy Quality Alliance (PQA). The measure was submitted to the National Quality Forum for review by their Medication Management Steering Committee. The NQF Consensus Standards Committee endorsed this measure for five medication types in July 2009.

The Adherence rate measures the percentage of patients 18 years and older who met the Proportion of Days Covered (PDC) threshold of 80 percent during the measurement year. CMS made a few modifications to the PQA measure specifications, which are reflected in the calculation of the rate. First, Part D drugs do not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2) of the Act, except for smoking cessation agents. As such, these drugs were excluded from the analysis. Second, CMS adjusted enrollment based on the number of months the beneficiary was enrolled in the Part D contract. An overall adherence rate will be calculated along with adherence rates for different medication types: Angiotensin-converting enzyme (ACE) inhibitors or Angiotensin-receptor blockers (ARB), Biguanides, Sulfonylureas, Thiazolidinediones, and Statins.

Rate Summary website feature

This new feature on the Patient Safety Analysis Website will provide sponsors an 'at a glance' view of their performance in each of the patient safety measures across one or more Part D contracts based on each users' authorized access. Sponsors can quickly view a summary of their current rate for the most recent monthly report. The summary will highlight if the rate is worse than the average, the percentage

point difference from the previous month's rate, and the percentage point difference compared to the contract type average (such as standalone Prescription Drug Plan (PDP) or Medicare Advantage Prescription Drug Plan (MA-PD)). The Patient Safety Website User Guide posted on the website provides additional information about this feature.

Performance graphs

A performance graph will be available within each contract-level patient safety measure report which will allow sponsors to graphically trend their monthly rates over time and show how the rates compare to the contract type average over time.

Outlier notifications

CMS is beginning to communicate patient safety outlier notices at the contract level to sponsors who perform worse than (or equal to) certain outlier threshold rates for each of the patient safety measures. These outlier notifications will be emailed to sponsors and will contain a link to the Patient Safety Analysis Website, through which sponsors are required to submit a response form for every identified outlier, describing a plan for improvement or reasons for the outlier rate. All authorized users of the Patient Safety Analysis Website for a sponsor with outlier(s) will receive the email notifications. Outliers will be identified shortly after each monthly report update. While these outlier notices do not constitute compliance actions, failure to respond or to provide sufficient responses may result in compliance actions.

For information on the methodology to define outlier threshold rates and to identify outlier contracts, refer to the 'Patient Safety Analysis: Methodology for Identifying Outliers' document located in the Help Documents section of the website. A Patient Safety Website User Guide is also posted on the website with information on how to view and respond to outlier issue notifications.

Access to the Patient Safety Analysis Website

To access the Patient Safety Reports and outlier notices, you must be an authorized user of the Patient Safety Analysis Website. CMS' contractor, Acumen, LLC, currently manages multiple websites for Medicare Part D contracts, including the Patient Safety Analysis Website. In accordance with Federal Information Security Management Act (FISMA) regulations, only the Medicare Compliance Officer is authorized to give access to these websites for each contract.

To streamline this process, Acumen has developed the User Security website – a web tool that allows Medicare Compliance Officers to manage their users on the Part D websites. To add users and assign them permissions to the Patient Safety Analysis Website, you must log onto the User Security Website (https://partd.programinfo.us/User_Security). For security purposes, each contract is allowed up to five users.

- **If your contract is continuing from CY2009**, currently authorized users will maintain their access to the Patient Safety Analysis Website through the transition to CY2010. You may choose to keep the same users or you may modify users.
- **If your contract is new in CY2010**, you must authorize new users for the Patient Safety Analysis Website.

Once users have been added, Acumen will send these authorized Patient Safety Analysis Website users:

- An email with the website user guide
- A letter with login credentials via USPS

Any general questions related to this Patient Safety Analysis project should be sent via email to PartDMetrics@cms.hhs.gov. For technical questions related to website or report access, please contact Acumen at PatientSafety@AcumenLLC.com or by phone at (650) 558-8006.

Thank you for your continued dedication to helping our beneficiaries.

Attachment 1: Medication Lists

The tables provided below are from the Pharmacy Quality Alliance (PQA) measure concept specifications. Part D drugs do not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2) of the Act, except for smoking cessation agents. As such, these drugs which may be included in the PQA lists were excluded from the CMS analyses.

Diabetes Medication Dosing (DMD) Medication List

Table 1-A: Biguanide Medications

Biguanides	
• metformin	
Biguanide & Sulfonylurea Combination Products	
• glipizide & metformin	• glyburide & metformin
Biguanide & Thiazolidinedione Combination Products	
• rosiglitazone & metformin	• pioglitazone & metformin
Biguanide & Meglitinide Combinations	
• repaglinide & metformin	
Biguanide & DPP-IV Inhibitor Combinations	
• sitagliptin & metformin	

Note: Active ingredients are limited to oral formulations only (includes all dosage forms).

Table 1-B: Biguanide Dosing

Medication	Maximum Dose (component 1)	Maximum Dose (component 2)
metformin IR	2,550mg/day	n/a
metformin ER and XR	2,000mg/day (up to 2,500mg/day for Fortamet)	n/a
glyburide & metformin	20mg/day (glyburide)	2,000mg/day (metformin)
glipizide & metformin	20mg/day (glipizide)	2,000mg/day (metformin)
repaglinide & metformin	10mg/day (repaglinide)	2,500mg/day (metformin)
sitagliptin & metformin	100mg/day (sitagliptin)	2,000mg/day (metformin)
pioglitazone & metformin IR	45mg/day (pioglitazone)	2,550mg/day (metformin IR)
pioglitazone & metformin ER	45mg/day (pioglitazone)	2,000mg/day (metformin ER)
rosiglitazone & metformin	8mg/day (rosiglitazone)	2,000mg/day (metformin)

*IR includes immediate release tablets/solution.

Update Reference: Drug Facts and Comparisons© 2010 by Wolters Kluwer Health, Inc. at www.factsandcomparisons.com (accessed 8/19/2010).

Table 2-A: Sulfonylurea Medications

Sulfonylureas	
<ul style="list-style-type: none"> • acetohexamide • chlorpropamide • glimepiride • glipizide 	<ul style="list-style-type: none"> • glyburide • tolazamide • tolbutamide
Sulfonylurea & Biguanide Combination Products	
• glipizide & metformin	• glyburide & metformin
Sulfonylurea & Thiazolidinedione Combination Products	
• rosiglitazone & glimepiride	• pioglitazone & glimepiride

Note: Active ingredients are limited to oral formulations only (includes all salts and dosage forms).

Table 2-B: Sulfonylurea Dosing

Medication	Maximum Dose (component 1)	Maximum Dose (component 2)
acetohexamide	1.5g/day	n/a
chlorpropamide	750mg/day	n/a
glimepiride	8mg/day	n/a
glipizide IR	40mg/day	n/a
glipizide XL	20mg/day	n/a
glyburide (non-micronized)	20mg/day	n/a
micronized glyburide	12mg/day	n/a
tolazamide	1,000mg/day	n/a
tolbutamide	3g/day	n/a
glyburide & metformin	20mg/day (glyburide)	2,000mg/day (metformin)
glipizide & metformin	20mg/day (glipizide)	2,000mg/day (metformin)
pioglitazone & glimepiride	45mg/day (pioglitazone)	8mg/day (glimepiride)
rosiglitazone & glimepiride	8mg/day (rosiglitazone)	4mg/day (glimepiride)

Update References: Drug Facts and Comparisons© 2010 by Wolters Kluwer Health, Inc. at www.factsandcomparisons.com (accessed 8/19/2010). Acetohexamide Dosing. <http://www.drugs.com/mmx/acetohexamide.html> (accessed 8/19/2010).

Table 3-A: Thiazolidinedione Medications

Thiazolidinediones	
<ul style="list-style-type: none"> • pioglitazone rosiglitazone 	
Thiazolidinedione & Biguanide Combination Products	
• rosiglitazone & metformin	• pioglitazone & metformin
Thiazolidinedione & Sulfonylurea Combination Products	
• rosiglitazone & glimepiride	• pioglitazone & glimepiride

Note: Active ingredients are limited to oral formulations only (includes all dosage forms).

Table 3-B: Thiazolidinedione Dosing

Medication	Maximum Dose (component 1)	Maximum Dose (component 2)
pioglitazone	45mg/day	n/a
pioglitazone & metformin IR*	45mg/day (pioglitazone)	2,550mg/day (metformin IR)
pioglitazone & metformin ER	45mg/day (pioglitazone)	2,000mg/day (metformin ER)
pioglitazone & glimepiride	45mg/day (pioglitazone)	8mg/day (glimepiride)
rosiglitazone & glimepiride	8m/day (rosiglitazone)	4mg/day (glimepiride)
rosiglitazone & metformin	8mg/day (rosiglitazone)	2,000mg/day (metformin)
rosiglitazone	8mg/day	n/a

*IR includes immediate release tablets/solution.

Update References: Drug Facts and Comparisons© 2010 by Wolters Kluwer Health, Inc. at www.factsandcomparisons.com (accessed 8/19/2010).

Drug-Drug Interaction (DDI) Measure Medication List

Table 1: Target and Precipitant drugs or Drug Classes

Target Drug or Drug Class (Step 1)	Precipitant Drug or Drug Class (Step 2)
Benzodiazepines: alprazolam, midazolam, triazolam	Azole antifungal agents: ketoconazole, itraconazole, fluconazole, posaconazole, voriconazole
carbamazepine	propoxyphene
cyclosporine	Rifamycins: rifampin, rifabutin, rifapentine
digoxin	clarithromycin, erythromycin, azithromycin, telithromycin
Ergot alkaloids: ergotamine, dihydroergotamine	clarithromycin, erythromycin, telithromycin
Estrogen/progestin oral contraceptives: desogestrel-ethinyl estradiol, drospirenone-ethinyl estradiol, estradiol valerate-dienogest, ethinyl estradiol-ethynodiol, ethinyl estradiol-levonorgestrel, ethinyl estradiol-norethindrone, ethinyl estradiol-norgestimate, ethinyl estradiol-norgestrel, mestranol-norethindrone	Rifamycins: rifampin, rifabutin, rifapentine
MAO Inhibitors: isocarboxazid, linezolid, phenelzine, rasagiline, selegiline, tranylcypromine	Sympathomimetics: amphetamines, atomoxetine, benzphetamine, dextroamphetamine, diethylpropion, isometheptene, methamphetamine, methylphenidate, phendimetrazine, phentermine, phenylephrine, pseudoephedrine, tapentadol, dexmethylphenidate, lisdexamfetamine Serotonergic Agents: buspirone, citalopram, cyclobenzaprine, desvenlafaxine, dextromethorphan, duloxetine, escitalopram, fluoxetine, fluvoxamine, meperidine, milnacipran, mirtazapine, paroxetine, sertraline, sibutramine, tetrabenazine, tramadol, trazodone, venlafaxine
methotrexate	trimethoprim/sulfamethoxazole
Nitrates: amyl nitrite, isosorbide dinitrate, isosorbide mononitrate, nitroglycerin	Phosphodiesterase inhibitors: sildenafil, tadalafil, vardenafil
simvastatin (40mg & 80mg)	amiodarone
tamoxifen	bupropion, duloxetine, fluoxetine, paroxetine
theophylline	ciprofloxacin, fluvoxamine
mercaptopurine	allopurinol
warfarin	cimetidine, trimethoprim/sulfamethoxazole, Fibrates: fenofibrate, fenofibric acid, gemfibrozil, NSAIDs: diclofenac, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, meclizolam, mefenamic acid, meloxicam, nambumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin

Note: Includes combination products and the following routes of administration: oral, sublingual, nasal, self-injectable (dihydroergotamine), rectal, buccal, transdermal, inhaled and translingual. Does NOT include OTC products, bulk powder products and excludes the following routes of administration: IV, IM, injectable, external (with the exception of transdermal nitroglycerine patch/ointment), ophthalmic and OTIC
MAO = mono-amine oxidase. NSAIDs = non-steroidal anti-inflammatory drugs.