

# Pharmacy Compliance manager

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Latest OPPTS Updates  
from CMS

Strategies for  
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Medicare News

### Worth Checking Out...

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This unique online tool greatly simplifies and speeds up the task of locating current coding, pricing and billing information for approximately 22,700 drugs. Visit the MedLearn Web Store ([shop.medlearn.com](http://shop.medlearn.com)) for all the details and a free trial.

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## DEA ISSUES NEW RULES FOR E-PRESCRIBING: Pharmacies Have Key Responsibilities

The Drug Enforcement Administration (DEA) recently issued an interim final rule governing the use of electronic prescriptions for controlled substances, including important provisions directed specifically at pharmacies. The agency intends the rule to facilitate the use of modern technology with its associated benefits of reducing errors and forgeries related to handwritten prescriptions.

DEA emphasizes that the regulations in the final rule are *in addition to*, not replacement of, existing regulations for controlled substance prescriptions. Accordingly, the FDA cites one of its current regulations: “The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”

The interim final rule has an effective date of June 1, 2010. That date may change, however, since the rule is subject to congressional review. Watch this newsletter for updates.

### Digital Signatures

The new regulations require either the pharmacy or the last intermediary routing an electronic prescription to digitally sign it, and the pharmacy must archive the digitally signed prescription as proof that it was received. Doing so allows DEA to determine if a prescription was altered during transmission or after receipt at the pharmacy. Approximately one-third of registered pharmacies have the ability to digitally sign electronic controlled substance orders through DEA’s system.

### CSA Database

Originally, DEA proposed that pharmacies check the Controlled Substance Act (CSA) database to confirm a prescriber’s valid DEA registration. Industry representatives balked at this requirement because such a registration check is not required for paper prescriptions. In response, DEA removed the proposed registration confirmation.

Pharmacists, of course, still must confirm that the controlled substance prescription contains the prescriber’s DEA registration number. DEA advises pharmacies that have doubts about a particular DEA registration to go to its Web site and use its Registration Validation Tool instead of purchasing the CSA database (<http://www.deadiversion.usdoj.gov/drugreg/index.html>).

### Audit Trails

The interim final rule requires that pharmacy software applications have an internal electronic audit trail that documents when a controlled substance prescription is received, annotated, modified, or deleted. The program must record when the annotation, modification, or deletion occurred and who took the action. In the rule’s comments, both pharmacy and software industry representatives expressed the importance of audits as a security tool.

### Offsite Storage

In response to strong objections, DEA removed its earlier proposed requirement that pharmacies store back-up records at a separate off-site location. The agency does, however, recommend off-site storage of back-up records as a best practice to prevent their loss should a natural disaster, fire, or system failure occur.

### Transfers

In the final rule, DEA states that it will make no change to existing policy concerning the transfer of controlled substance prescriptions. This still requires communication between two licensed pharmacists even when the two pharmacies share a database—for example, pharmacies in the same health system. The transferring pharmacy must note in its records to which pharmacy it is transferring the prescription, and the receiving pharmacy must note the pharmacy from which it received the transfer.

**Information Source:** The interim final rule is available from the Federal Register Web site at <http://edocket.access.gpo.gov/2010/pdf/2010-6687.pdf>.

## QUARTERLY UPDATE TO HOSPITAL OPPTS: Many Changes Related to Pharmacy Billing

A handful or two of changes and several billing reminders are included in the April 2010 update to the hospital outpatient prospective payment (OPPS) system. In Transmittal R1924CP (February 26), the Centers for Medicare & Medicaid Services (CMS) address several issues, including the following, that should be passed along to billing staff.

### Warfarin Testing

As you know from previous newsletter articles (January 2010 and October 2009), on April 5, 2010, CMS implemented a Medicare policy related to pharmacogenomic testing to predict warfarin (Coumadin®) responsiveness. As noted, it's only covered in the context of an approved, clinical study. The effective date for the policy goes back to August 3, 2009.

In the April update, CMS reminded providers to report the study with HCPCS Level II code G9143—warfarin responsiveness testing by genetic technique using any method, any number of specimen(s). It also indicated that payment will be made under the clinical lab fee schedule (CLFS), but the code and rate do not yet appear there. So, for 2010, Medicare fiscal intermediaries (FIs) and/or A/B Medicare administrative contractors (MACs) will determine and post payment for G9143.

### Payment Rates Updated

As always in the quarterly updates, CMS lists codes that had incorrect payment rates somewhere back in time. Such is the case in this latest update. To submit a request for the corrected rate, claims must have been processed before April 1, 2010.

CMS noted a correction for the rate for one code for the period January 1 through March 31, 2009. The previous rate is noted in parenthesis below the current rate in the second column in the following table.

J9031	BCG (intravesical) per instillation	\$118.96 (\$108.55)
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The following corrected payment rates apply to the period from October 1 through December 31, 2009.

90371	Hepatitis B immune globulin (HBIG), human, for intramuscular use	\$113.78 (\$111.20)
J1458	Injection, galsulfase, 1 mg	\$333.49 (\$339.04)
J2278	Injection, ziconotide, 1 microgram	\$ 6.38 (\$ 6.65)
J2323	Injection, natalizumab, 1 mg	\$ 7.97 (\$ 8.32)

### Pass-Through Status

Effective April 1, CMS granted OPPS pass-through status to the following codes. This means that they will receive a separate ambulatory payment classification (APC) rate, although that rate is not yet posted on the CMS web site.

Codes and Descriptions	
C9258	Injection, telavancin, 10 mg
C9259	Injection, pralatrexate, 1 mg
C9260	Injection, ofatumumab, 10 mg
C9261	Injection, ustekinumab, 1 mg
C9262	Fludarabine phosphate, oral, 1 mg
C9263	Injection, ecallantide, 1 mg

### Billing Reminders

Most of CMS's quarterly updates include the following billing tips related to drugs, biologicals, and radiopharmaceuticals. This repetition suggests that these guidelines are important and that providers often ignore them.

- Report charges for all drugs, biologicals, and radiopharmaceuticals, regardless of whether the items are paid separately or packaged, using the correct HCPCS codes for the items used.

- Make certain that the reported units of service of the reported HCPCS codes are consistent with the quantity that was used in the patient's care.
- Report units in multiples of the units included in the long HCPCS descriptor.
- Do not bill units based on the way the drug is packaged, stored, or stocked.
- If two or more drugs or biologicals are mixed together to facilitate administration, the correct HCPCS codes should be reported separately for each product used in the care of the patient. The mixing together of two or more products does not constitute a "new" drug as regulated by the Food & Drug Administration (FDA). Do not bill HCPCS code C9399 (unclassified drug or biological) for new drugs and biologicals that are approved by the FDA on or after January 1, 2004, for which a HCPCS code has not been assigned.
- Unless otherwise specified in the long description, HCPCS descriptions refer to the non-compounded, FDA-approved final product. If a product is compounded and a specific HCPCS code does not exist for the compounded product, the hospital should report an appropriate unlisted code such as J9999 or J3490.
- A code is not necessarily covered just because a payment rate is listed. Medicare contractors determine whether all program requirements for coverage have been met before issuing payment.

**Information Sources:** The official instructions can be found at <http://www.cms.hhs.gov/transmittals/downloads/R1924CP.pdf> and the provider-information memo at <http://www.cms.hhs.gov/MLN MattersArticles/downloads/MM6857.pdf>.

# RISK EVALUATION AND MITIGATION STRATEGIES:

## What Pharmacy Directors Need to Know

By Anne T. Jarrett, MS, RPh

In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA). It requires that manufacturers of certain drugs and biologicals provide evidence to the FDA demonstrating that the benefits of their products continue to outweigh the risks. Typically, the drugs and biologicals involved have demonstrated toxicities along with their associated risk factors. Before the passage of the act, private sponsors and companies were responsible for analyzing products to ensure patient safety.

REMS programs are required for both new and older designated drugs with these characteristics. To date, the FDA has asked manufacturers of over 89 products to create systematic plans that can be used to educate both patients and healthcare providers about drug toxicities and their associated risk factors.

These programs may contain the four possible components listed below:

- Medication guide;
- Communication plan;
- Elements to assure safe use (ETASU); and
- Implementation system.

While the components of REMS programs differ according to the level of severity of a product's risks and toxicities, all programs must contain a timetable for assessment.

The components and examples of each are discussed in more detail below. In 2010, the FDA so far has approved REMS for the drugs (and their required individual components) listed in the tables.

**Medication Guides.** The most common component of a REMS program is the provision of a medication guide, and a number of REMS programs contain only this requirement.

According to the Code of Federal Regulations (21 CFR Section 208), medication guides should be dispensed only to outpatients. The regulations also outline exemptions for when medication guides do not have to be dispensed. Both new prescriptions and refills are affected. The regulations may be found in their entirety at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=208>.

In addition, a complete list of medications that require medication guides may be found at: <http://www.fda.gov/cder/Offices/ODS/labeling.htm>.

Each medication guide must include an expressed goal. An example of such a goal is "to ensure that patients understand the risks of heart failure in patients being treated with pioglitazone containing products."

### Medication Guide Only

Drug	Date
Janumet (sitagliptin/metformin) tabs	February 26, 2010
Januvia (sitagliptin) tabs	February 26, 2010
Kaletra (lopinavir and ritonavir) tabs and oral sol	January 29, 2010
Lamictal XR (lamotrigine) tabs	January 29, 2010
Lyrica (pregabalin) caps and oral sol	January 4, 2010
Morphine sulfate oral solution	January 25, 2010
Oleptro (trazadone hydrochloride) ER tabs	February 2, 2010

**Communication Plans.** These are usually comprised of sending letters to prescribers and pharmacists. Here's an example of a communication plan: "The initial letters will be distributed within 60 days of the approval of Ampyra. Annual letters to both groups will be sent within 60 days of the anniversary date of approval for Ampyra and every year for the next three years."

### Medication Guide and Communication Plan

Drug	Date
Actemra (tocilizumab) tabs	January 8, 2010
Ampyra (dalfampridine) ER	January 22, 2010
Tasigna (nilotinib) caps	March 15, 2010
Victoza (liraglutide) inj	January 25, 2010
Xiaflex (collagenase clostridium histolyticum) inj	February 2, 2010

**ETASUs.** For REMS requiring ETASU, clinicians may be required to perform such tasks as the following:

- Obtaining and dispensing drugs through specific distribution channels;
- Possessing specific training, education, experience, or certification(s) in order to prescribe these drugs;
- Enrolling patients in registry programs; and
- Communicating mandatory, time-sensitive reports of patient responses to treatment.

### Medication Guide and ETASU

Drug	Date
Exalgo (hcl) ER tab	March 1, 2010

**Implementation Systems.** Examples of these vary but here's one: "Amgen will monitor issue compliance with documentation of the risk: benefit discussion and completion of the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form and will work to improve implementation of these elements if non-compliance is identified."

### Medication Guide, ETASU and Implementation Plan

Drug	Date
Promacta (eltrombopag) tabs	March 5, 2010
Tracleer (bosentan) tabs	February 19, 2010

### Medication Guide, Communication Plan, ETASU and Implementation Plan

Drug	Date
Aranesp (darbepoetin alfa) inj	June 1, 2010
Epogen/Procrit (epoetin alfa) inj	February 16, 2010

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# MEDICARE PAYMENTS AND POLICIES: Current Odds and Ends

Although short, the following information is important for pharmacy directors.

## Current ASP Files Posted

On March 18, the Centers for Medicare & Medicaid Services (CMS) posted *revised* average sales price (ASP) drug files for January 2010, October 2009, July 2009, and April 2009. The agency has also posted April 2010 pricing files. These files contain the payment amounts for Part B covered drugs effective for the applicable quarters. Note the following effective dates for each quarterly file.

Files	Effective Dates of Service
April 2010 ASP and NOC	April 1–June 30, 2010
January 2010 ASP and NOC	January 1–March 31, 2010
October 2009 ASP and NOC	October 1–December 31, 2009
July 2009 ASP and NOC	July 1–September 30, 2009
April 2009 ASP and NOC	April 1–June 30, 2009

## Information Sources:

- The transmittal announcing the above can be found at <http://www.cms.hhs.gov/Transmittals/downloads/R1922CP.pdf>;
- To download the quarterly files, go to [http://www.cms.gov/McrPartBDrugAvgSalesPrice/01a19\\_2010aspfiles.asp#TopOfPage](http://www.cms.gov/McrPartBDrugAvgSalesPrice/01a19_2010aspfiles.asp#TopOfPage).

## Resources for Standards Transition

CMS continues to update information on its web site dedicated to helping providers transition to new electronic transaction standards. Providers should be working now toward the first level of standard compliance targeted for implementation on December 31, 2010.

As reported in the article on page 2 of the July issue of this newsletter, providers must be completely compliant with three new standards—two of which apply specifically to pharmacy transactions—by January 1, 2012. To recap, the new standards include the following.

- Version 5010 is the new version of the X12 standards for HIPAA transactions.
- Version D.0 is the new version of the National Council for Prescription Drug Program (NCPDP) standards for pharmacy and supplier transactions.
- Version 3.0 is a new NCPDP standard for Medicaid pharmacy subrogation.

Testing checklists, frequently asked questions (FAQs), and announcements for Version 5010 provider-education calls are now available. While not as developed as the Version 5010 page, providers will also find separate web pages for Version D.0 and Version 3.0 implementation where CMS regularly adds new content.

For more information, go to <http://www.cms.hhs.gov/Versions5010andD0> and click “Educational Resources.”

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## Timetable for Submission

An example of a timetable for submission of assessments is “REMS assessments will be submitted to FDA at 18 months, 3 years, and 7 years after approval.”

**Information Source:** For more on the above, check the FDA website at: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm>

*gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm*

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## Comments, Questions?

*MedLearn welcomes your input about this newsletter. If you have any comments regarding its content or have technical or coding questions you'd like answered, please call Janis Oppelt at 1-800-252-1578, ext. 3016.*

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