Wednesday, October 3, 2012
9:00 AM - 10:30 AM

208 – Current Pharma Trends: More Paper, More Reporting and More Sunshine

Richard Cheng
General Counsel
Senior Care Centers

Maria Gonzalez Knavel
Partner
Foley & Lardner LLP

Margaret Richardson
Vice President, Legal
Qualitest Pharmaceuticals

David Rosen
Partner
Foley & Lardner LLP

Faculty Biographies

Richard Cheng

Richard Cheng, JD,OTR/L is the general counsel and a senior executive member at Senior Care Centers, based in Dallas, TX. Previously, he was the general counsel and vice president of medical appeals at Century Rehabilitation and an associate attorney at Pearson Randall & Schumacher & LaBore, P.A. where he practiced civil litigation and worked as a corporate staff attorney for Thomson Reuters, Inc.

Mr. Cheng has successfully conducted multiple trials, won the 2011 Best Corporate Counsel Rising Star for the *Dallas Business Journal*, won the 2012 National Diversity Council Legal Diversity Champion Award and recognized as a finalist for the *D CEO Magazine*/ACC best corporate counsel award. In addition, he was recognized by Texas Tech Health Sciences Center for the 2010 Distinguished Alumni Award and received the 2011 Texas Occupational Therapy Association Distinguished Service Award.

Prior to his legal career, Mr. Cheng worked as a licensed occupational therapist in rehabilitation, acute care, long term care, outpatient and home health care. He has served as an adjunct faculty at Saint Catherine University and Nova Southeastern University and has lobbied in Washington D.C. through the American Occupational Therapy Association.

He received his JD degree from Nova Southeastern University Shepard Broad Law Center as a Goodwin Scholar and his BS/MOT degrees from Texas Tech University Health Sciences Center.

Maria Gonzalez Knavel

Maria E. Gonzalez Knavel is a partner with Foley & Lardner LLP. A member of the firm's health care and life sciences industry teams and government enforcement, compliance and white collar defense practice, she counsels health care clients on compliance issues, corporate matters and general operational issues of health care entities (including providers and medical device manufacturers), and Medicare/Medicaid reimbursement. Prior to entering law school, she managed a medical clinic for 12 years.

Ms. Gonzalez Knavel's professional activities include national speaking engagements on a diversity of topics, including health care fraud, critical compliance issues and voluntary disclosure, as well as presentations to hospital and health care associations such as "Physician Contracting and Affiliations under Stark II" and "Tailoring the OIG Compliance Plan to Your Physician Practice."

She is the recipient of the 2010 Association of Women Lawyers (AWL) Community Involvement Award. This honor recognizes an attorney who demonstrates significant

involvement in organizations committed to strengthening and improving the quality of life for those in Milwaukee and Southeast Wisconsin. Ms. Gonzalez Knavel has also been selected by her peers for inclusion in the 2009-2012 editions of The Best Lawyers in America(R) in the area of health care law. In recognition of her experience, Ms. Gonzalez Knavel has been Peer Review Rated as AV(R) Preeminent ™, the highest performance rating in Martindale-Hubbell's peer review rating system.

Ms. Gonzalez Knavel is a graduate of Marquette University School of Law (JD), where she was a member of the *Marquette Law Review*, and Pennsylvania State University (BS, with distinction).

Margaret Richardson

Margaret Richardson is vice president of legal for the generics business unit of Endo Pharmaceuticals. Ms. Richardson is responsible for all legal issues in the generics business unit, which includes three manufacturing facilities, a distribution center, and over 600 SKUs.

Prior to joining Endo Pharmaceuticals, she was senior counsel at SurModics Pharmaceuticals, a contract manufacturing organization specializing in sterile fill. Prior to SurModics Pharmaceuticals, she was general counsel for both Jubilant Pharmaceuticals and Schwarz BioSciences. Ms. Richardson has spent more than 15 years in the pharmaceutical and life sciences industry starting on the business development side as a patent attorney and moving to the operations side as she gained experience and a deep understanding of the pharmaceutical business.

Currently, Ms. Richardson serves as the vice-president for the ACC’s Alabama Chapter, and vice-chair of the Health Law Committee.

David Rosen

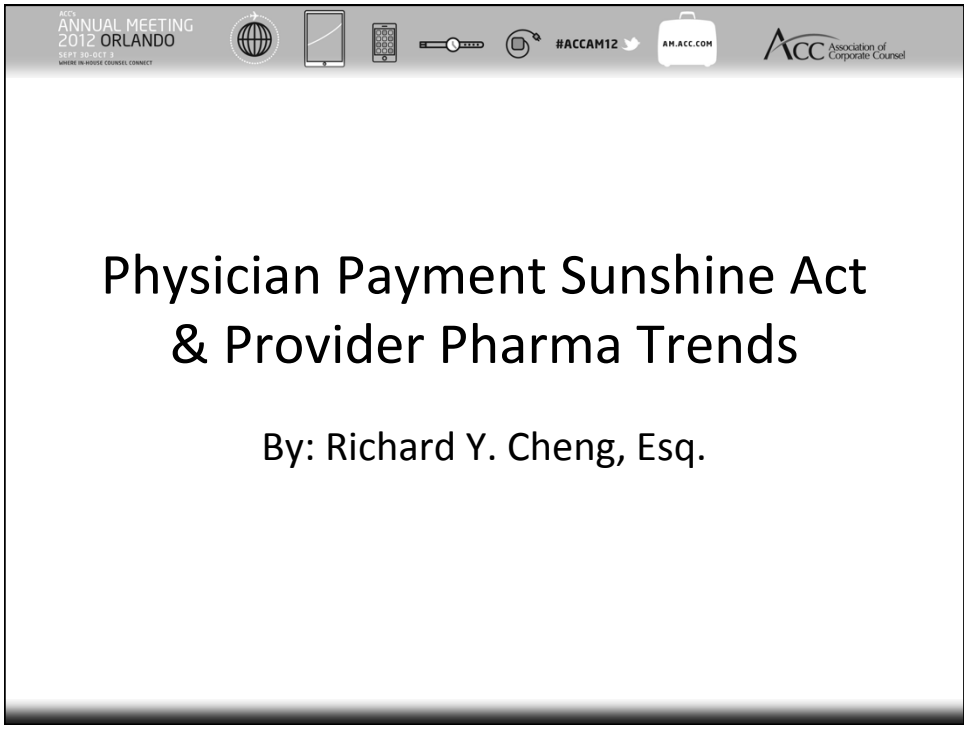
David Rosen is a partner, leader of the FDA practice and co-chair of the life sciences industry team at Foley & Lardner LLP. He is also a member of the firm's government and public policy practice and the health care, nanotechnology and food industry teams.

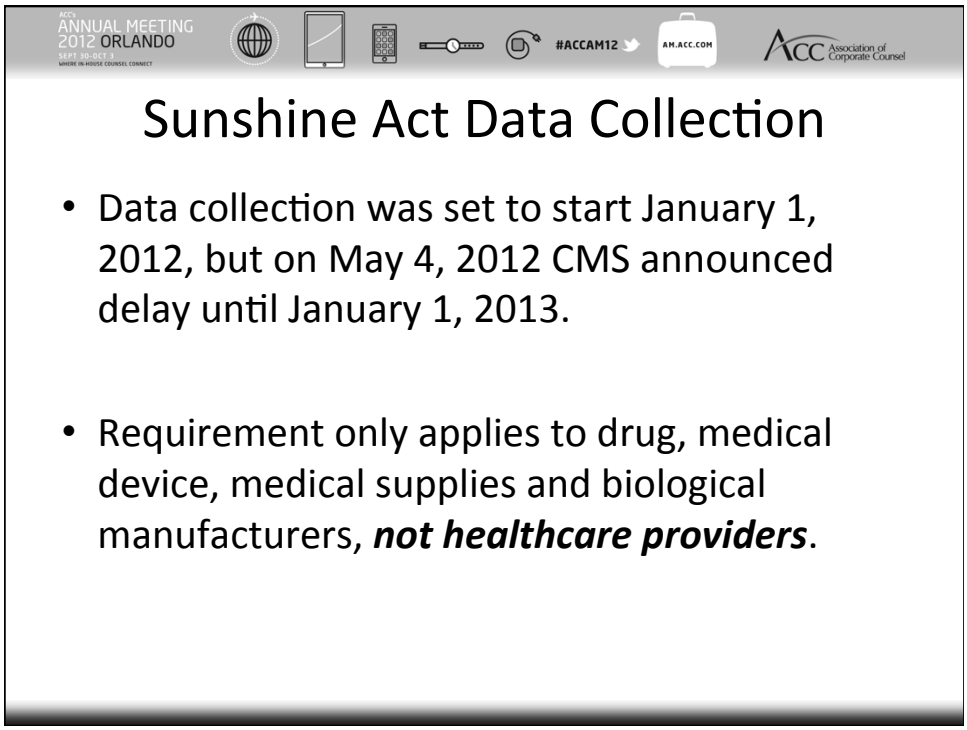
Mr. Rosen has extensive experience in health law, life sciences, and food and drug regulation, including a range of Food and Drug Administration (FDA) regulatory issues affecting prescription and over-the-counter pharmaceuticals, medical devices and biologics.

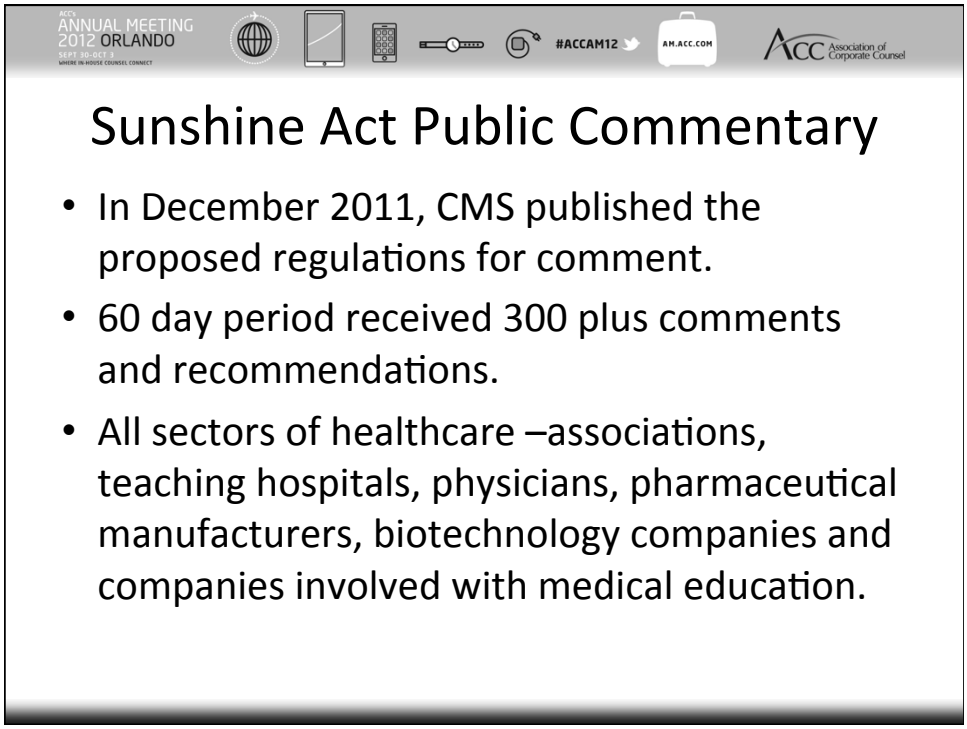
Mr. Rosen was also employed by the FDA, progressing to various supervisory positions involving virtually all aspects related to the drug approval process, combination products, jurisdictional issues and related compliance activities.

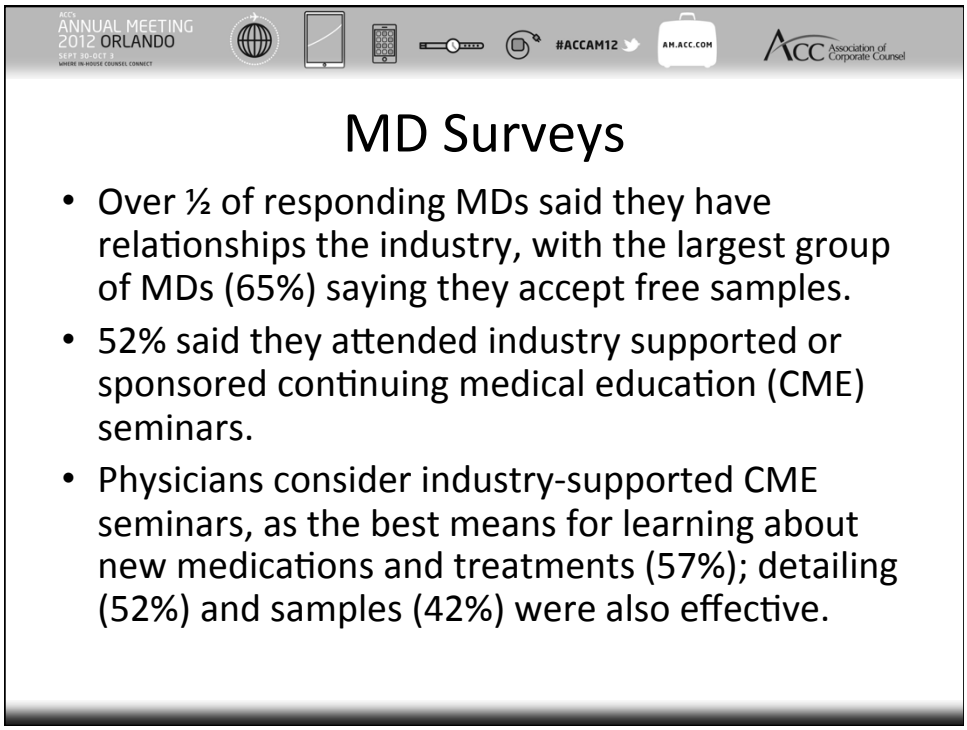
He has been a frequent speaker before national and international pharmaceutical industry associations on a wide variety of the FDA related issues.

Mr. Rosen earned his JD at The Catholic University of America, Columbus School of Law. He also holds a BS from the University of Connecticut School of Pharmacy. He is also a member of the University of Connecticut School of Pharmacy advisory board.



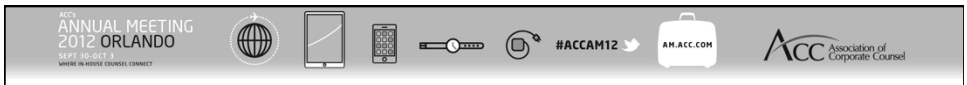






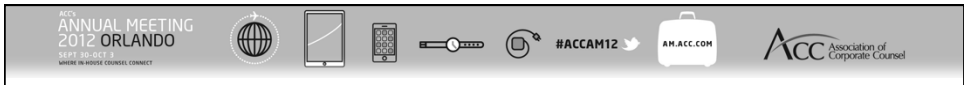
MD Surveys Continue

- Majority (64%) said that disclosure for doctors should be mandatory, with an even greater percentage (83%) supporting mandatory disclosure for researchers.
- Interestingly, 44% supported mandatory disclosure for nurses, which are not covered by the Sunshine Act disclosure requirements.
- One-third (31%) of those surveyed stated that they were unclear about how the PPSA disclosure requirements operated.



Companies Survey

- Three-quarters of the respondents said to comply with HCP disclosure requirements their investment over the next two years (2012-2013) would equal or surpass 2011 expenditure.
- Greater than three-quarters of the respondents said they see training programs and software integration and upgrades as consuming the greatest proportion of this increased compliance investment, while 25% also noted that they will be hiring new full-time employees in legal, sales, marketing and IT to work on compliance programs

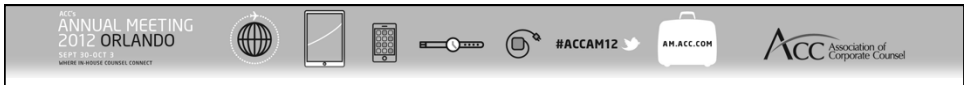


What Does This Mean?

- Expend significant time, effort, and resources complying with PPSA.
- Health care providers and the life sciences industry will be challenged to figure out how to achieve compliance in the most efficient, cost-effective manner."
- Most important consideration for the life sciences industry [may be] that the PPSA provides an opportunity to evaluate spending allocations for health care provider relationships.

Health Care Provider Pharmacy Concerns

- Fraud and abuse
- Pharmacies will publish a formulary (list of preferred medications) for cost containment (for the customer) and for safety.
- Pharmacies assess the cost, medical benefits and safety of all the drugs on their formulary.
- Drug manufacturers provide rebates to pharmaceutical companies to motivate them to endorse the use of their drugs.

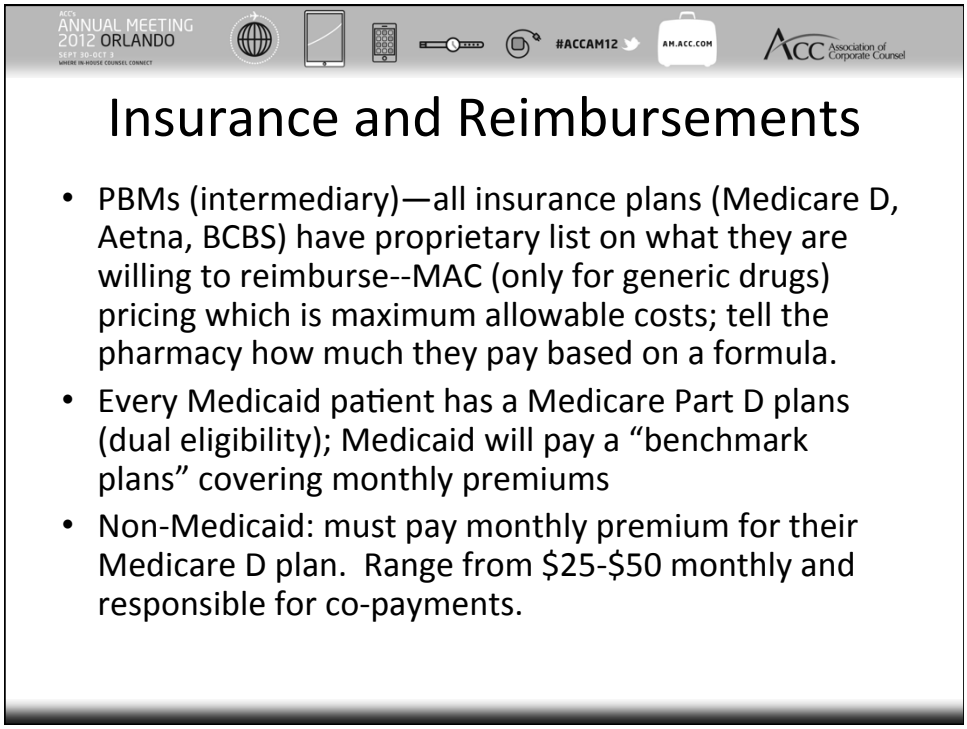


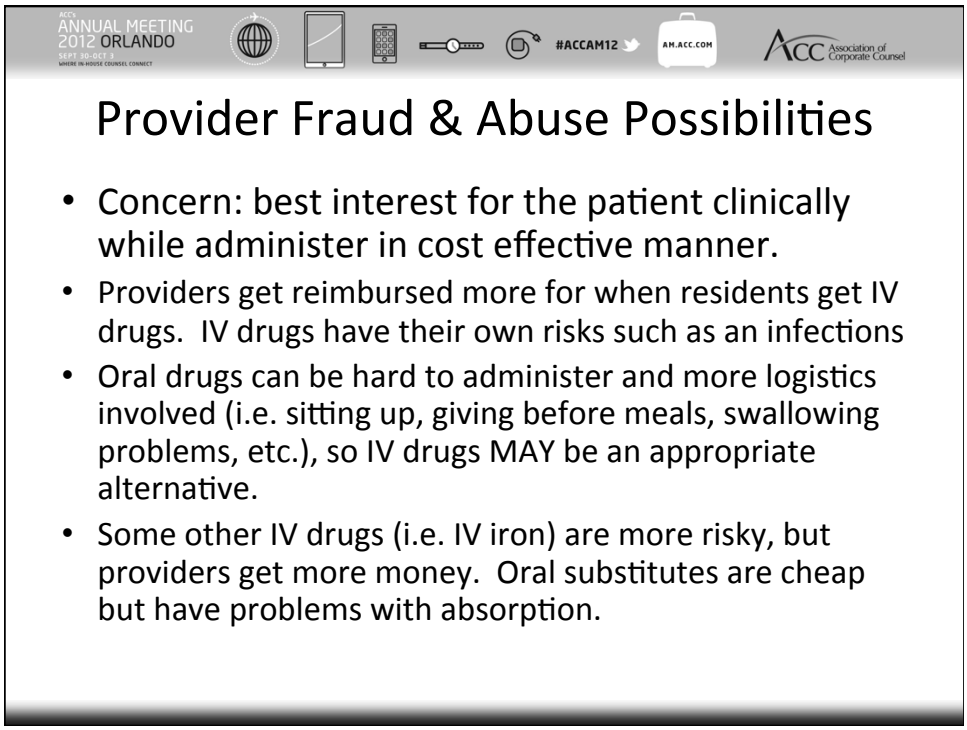
Rebates

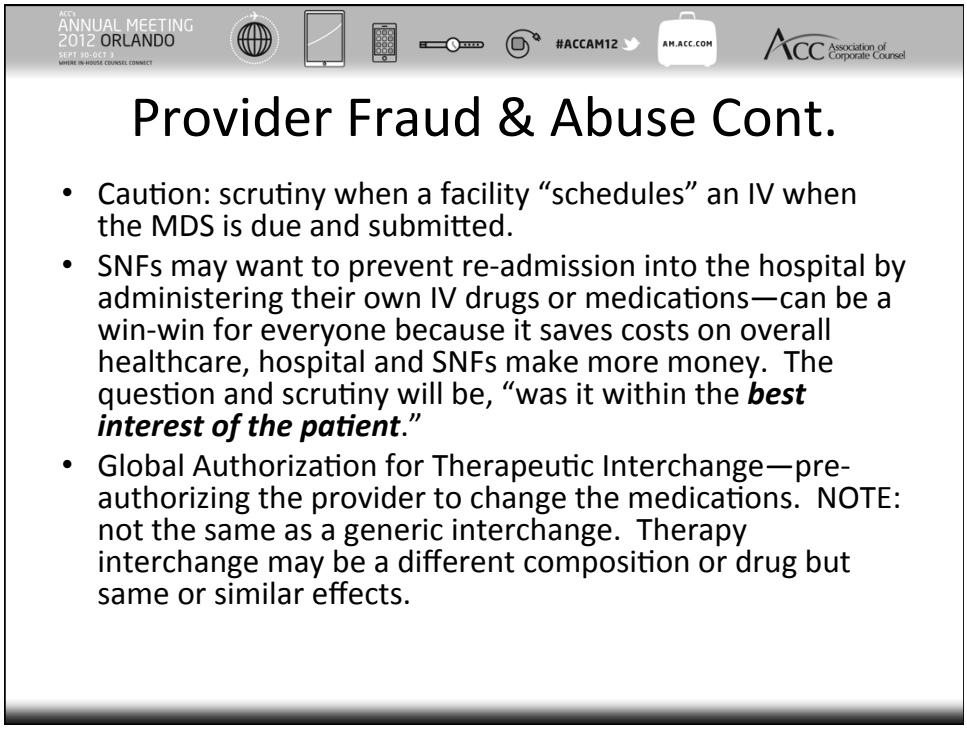
- Manufacturer rebates—based on market shares or market penetration within a particular class of drugs.
- Market Share Rebates—from group purchasing organizations (e.g. wholesalers, MHA, Cardinal); these come from WHs and manufacturers.

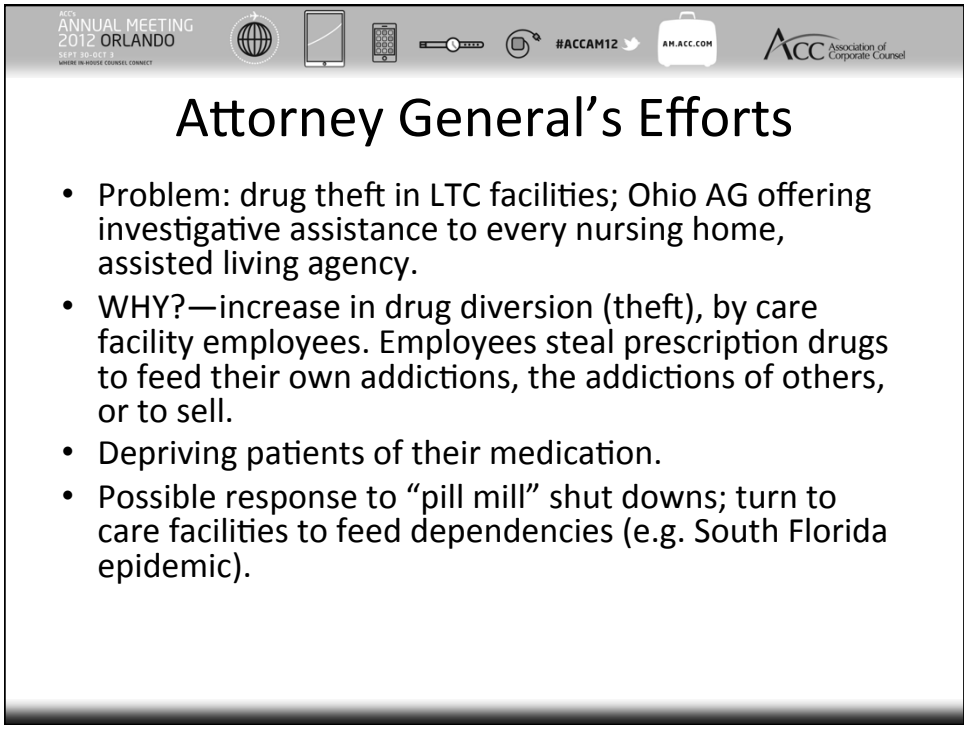
Pricing

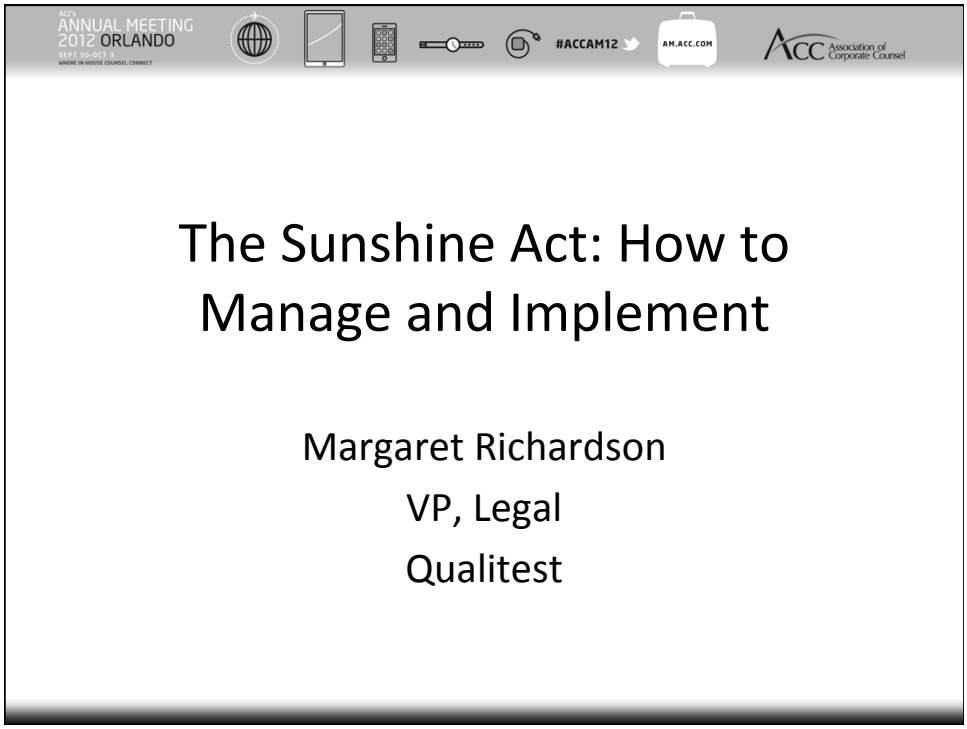
- Pharmacies use GPOs seek the lowest drug prices by moving large volumes of drugs from WHs or manufacturers.
- Customer's price is based on the published average wholesale price (AWP), which is dictated by the market.
- Customers—pay average wholesale price (AWP) which is dictated by the market
- Wholesale acquisition cost (WAC) may replace AWP; Actual acquisition cost (AAC), which is the actual price for the wholesaler.





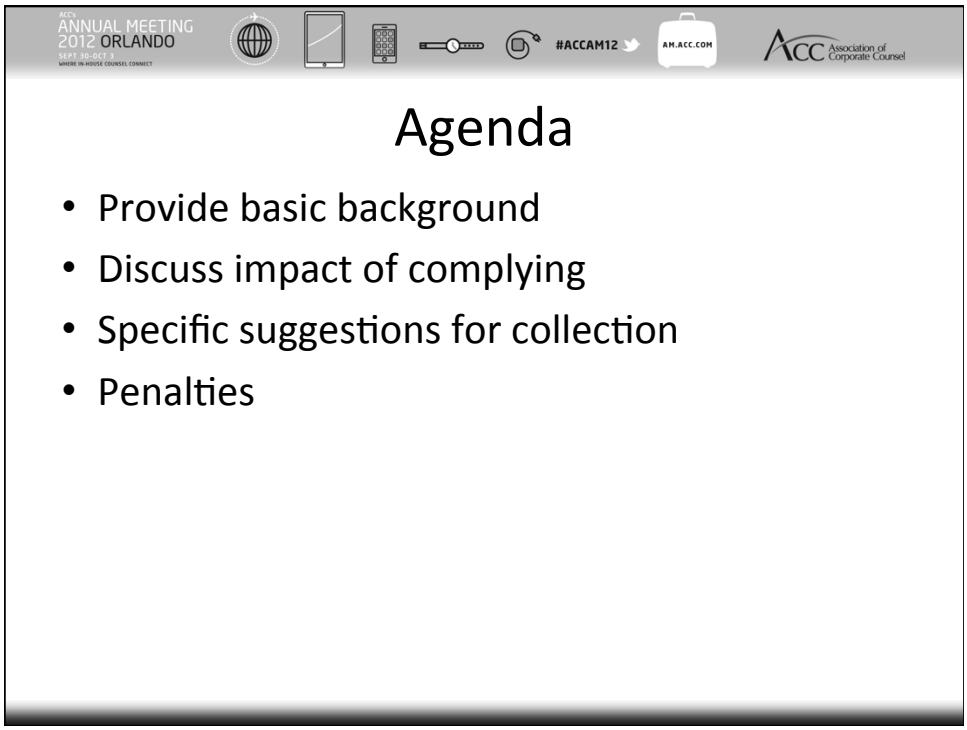






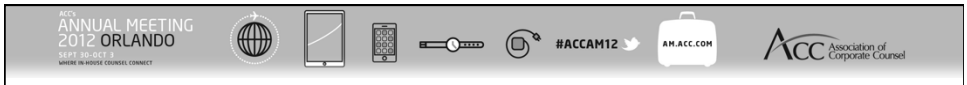
The Sunshine Act: How to Manage and Implement

Margaret Richardson
VP, Legal
Qualitest



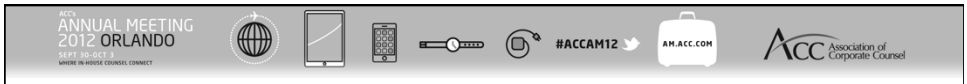
Agenda

- Provide basic background
- Discuss impact of complying
- Specific suggestions for collection
- Penalties



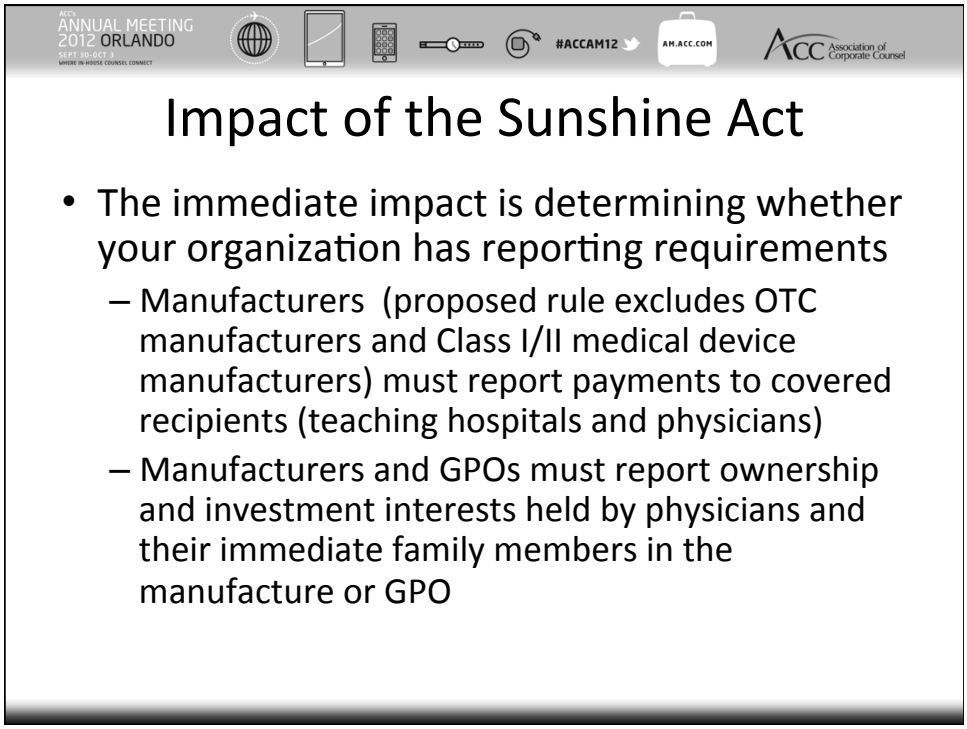
Basic Background

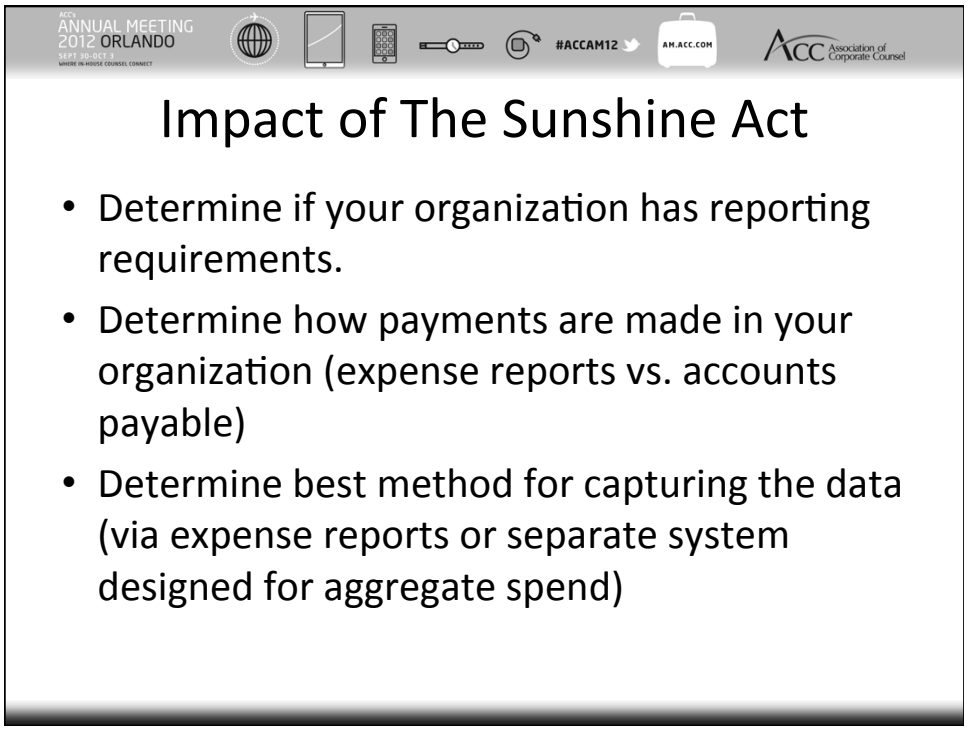
- The genesis of the Sunshine Act is the Patient Protection Affordable Care Act (H.R. 3590) passed on March 22, 2010
  - Specifically section 6002 of the Act
  - The Act states that any drug, device, or medical supply manufacturer operating in the United States must report any payment or benefit given to a physician.
  - Payments under $10 are excluded but only if the total spent on the HCP is less than $100 per year.

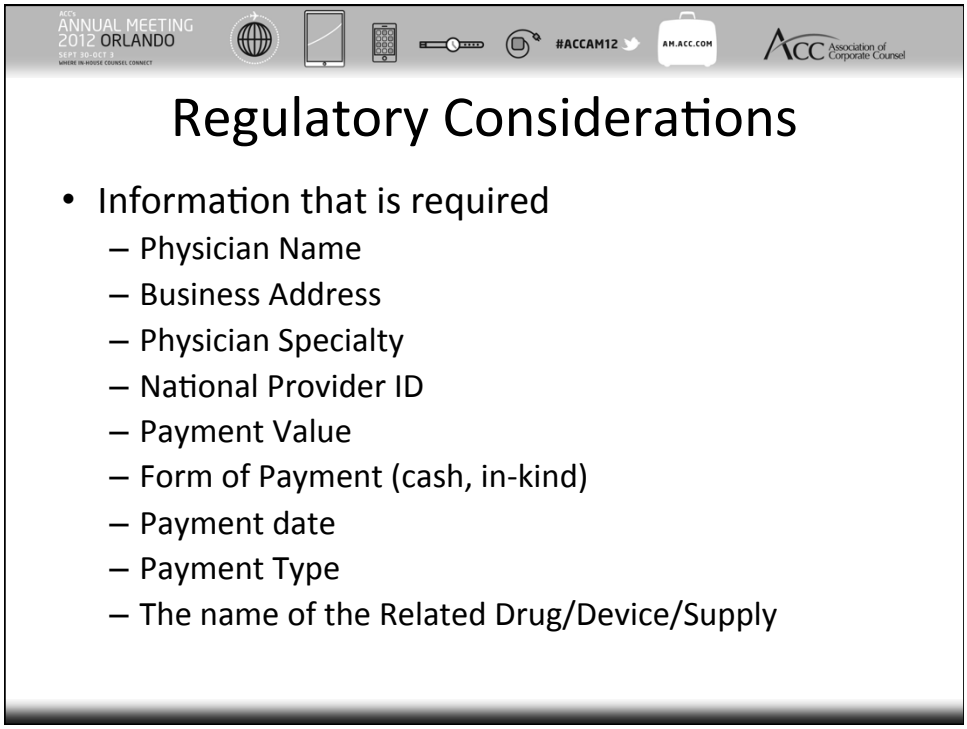


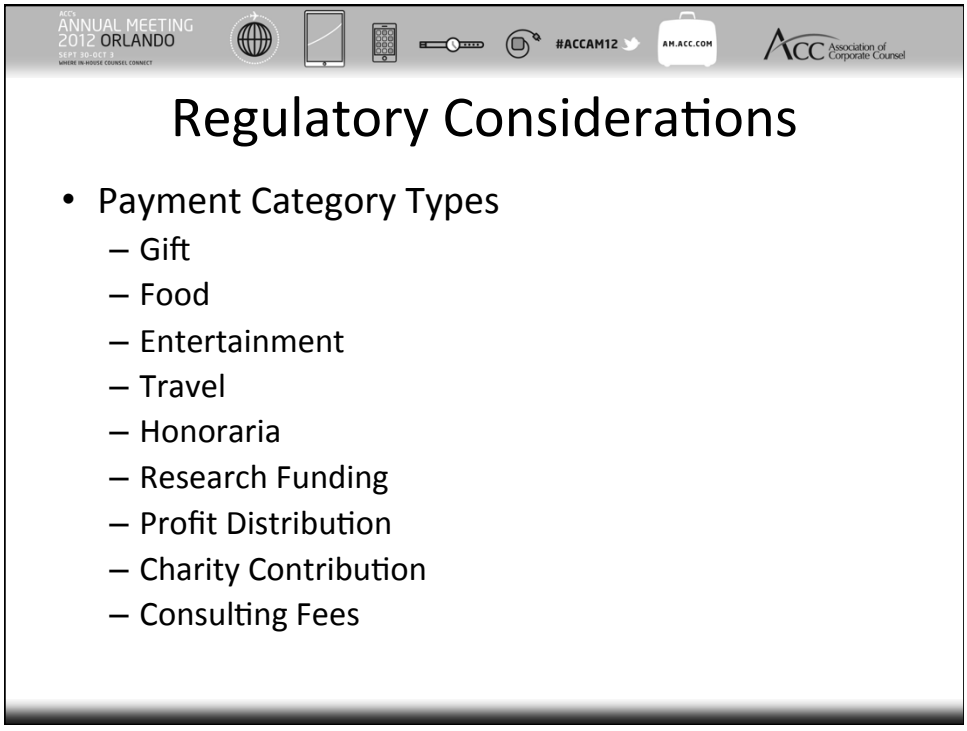
Basic Background

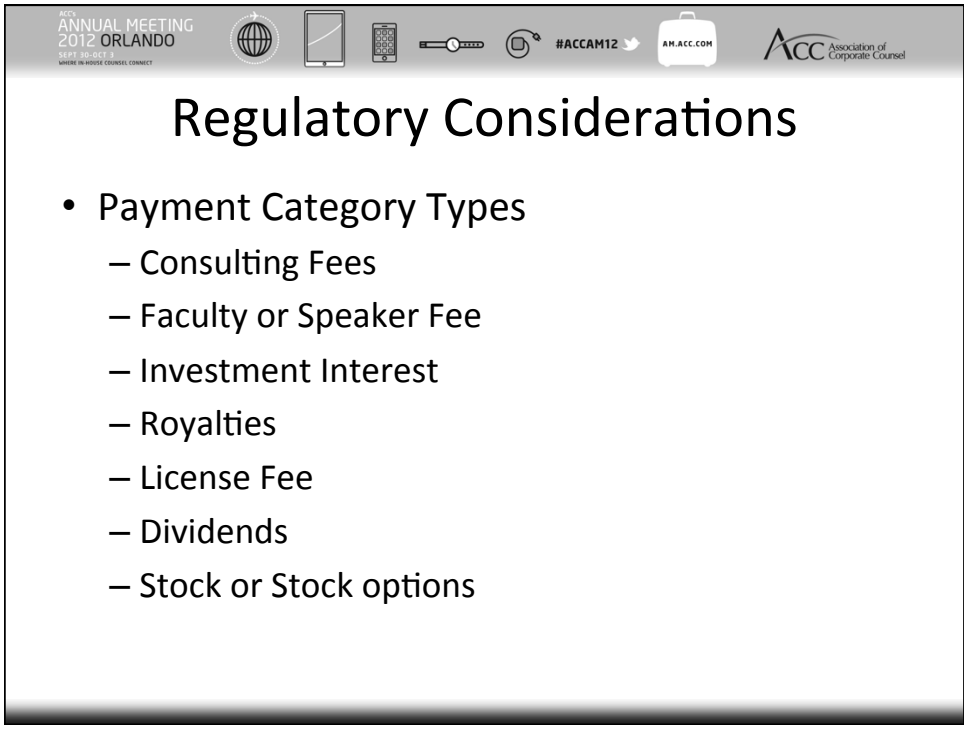
- Final rules have not yet been released.
- CMS has delayed the start date and has stated that it will not require the collection of information until after the final rule is published.
- Final comments were due on February 17, 2012.

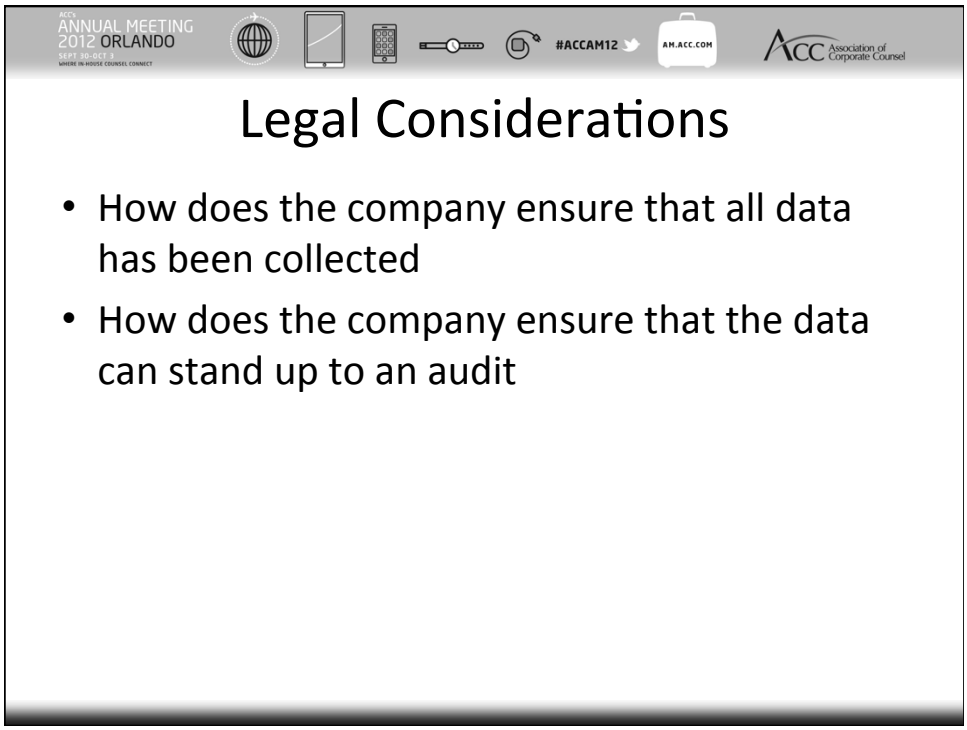


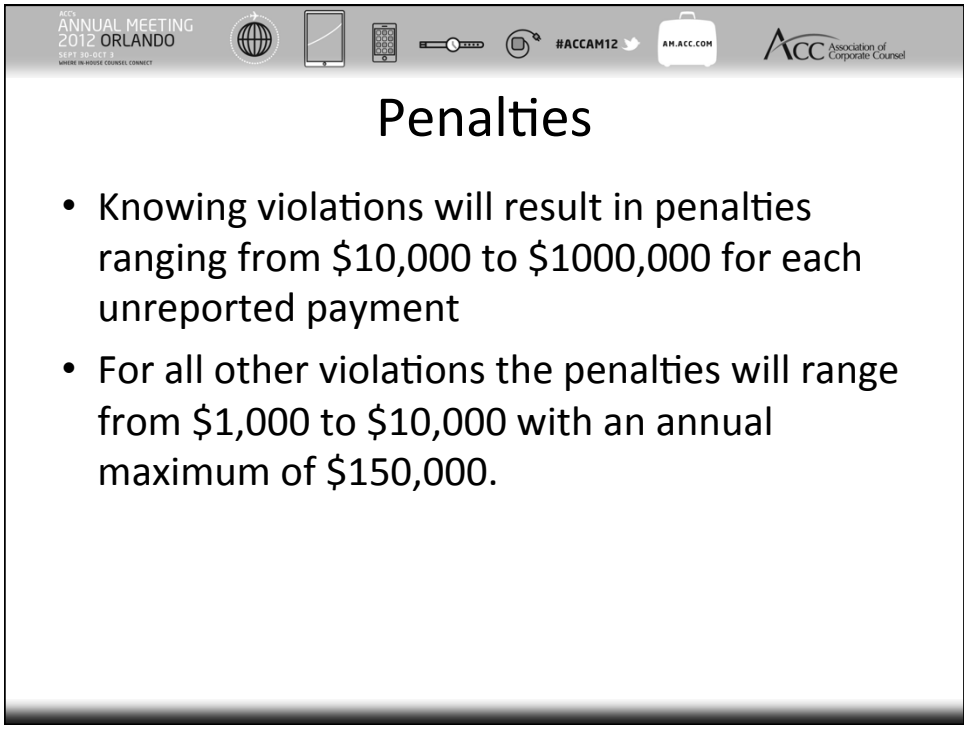


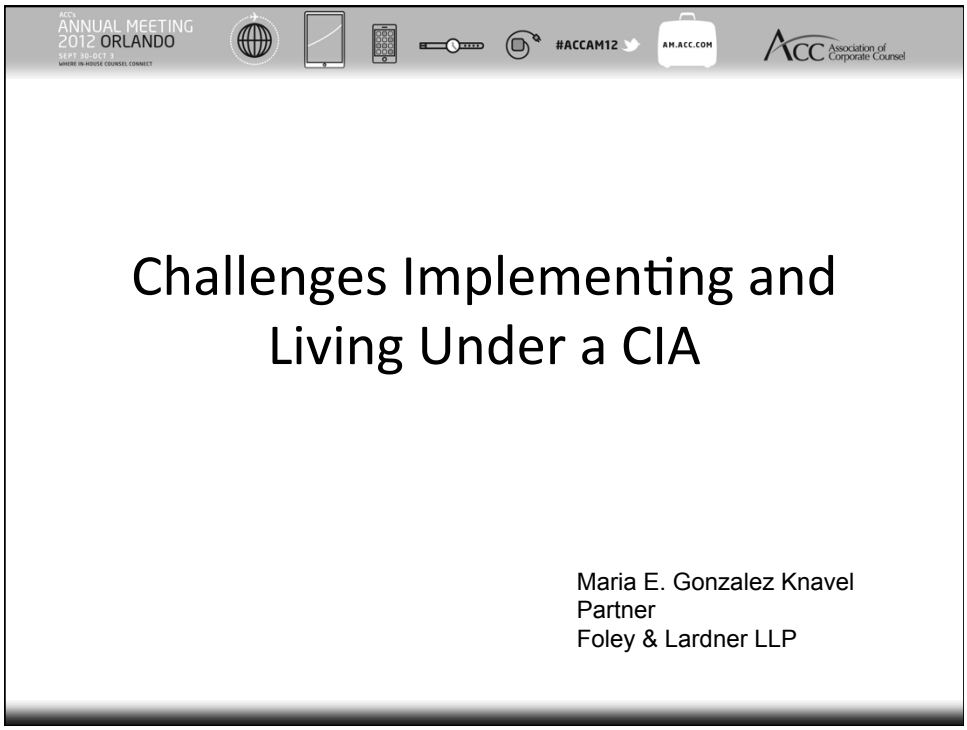


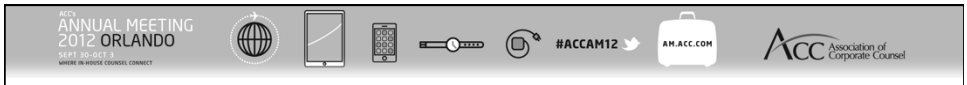










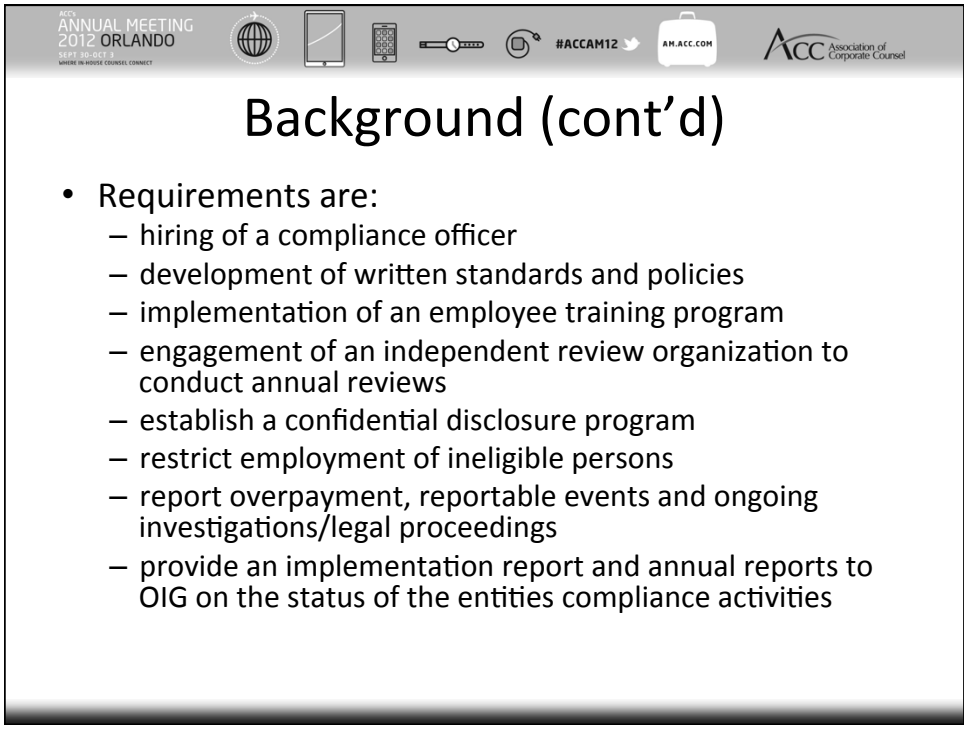


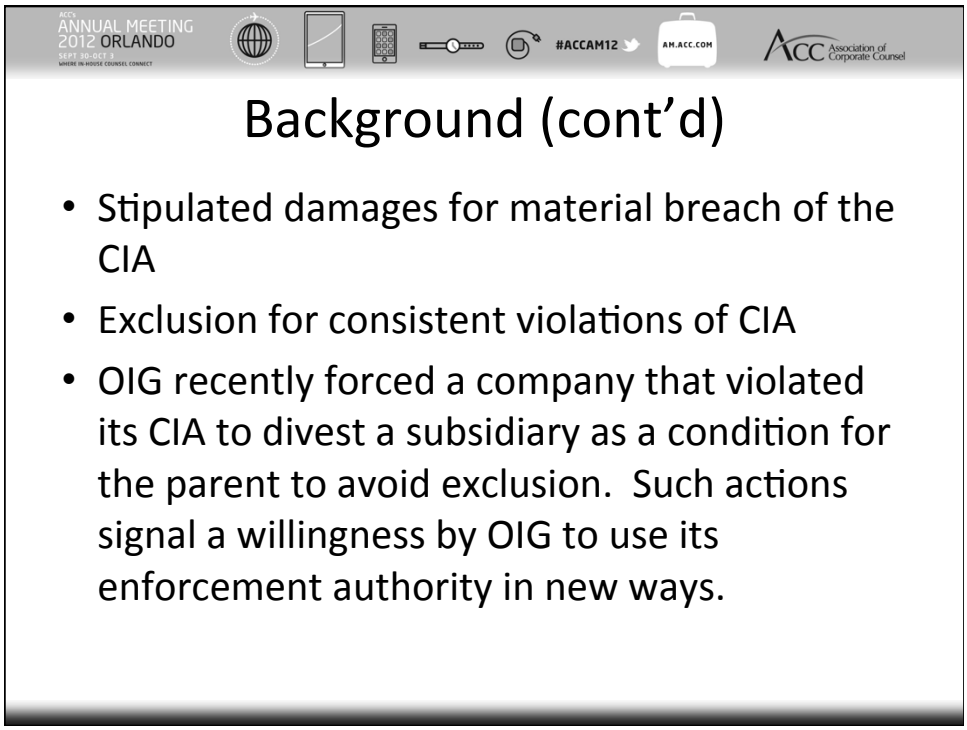
Background

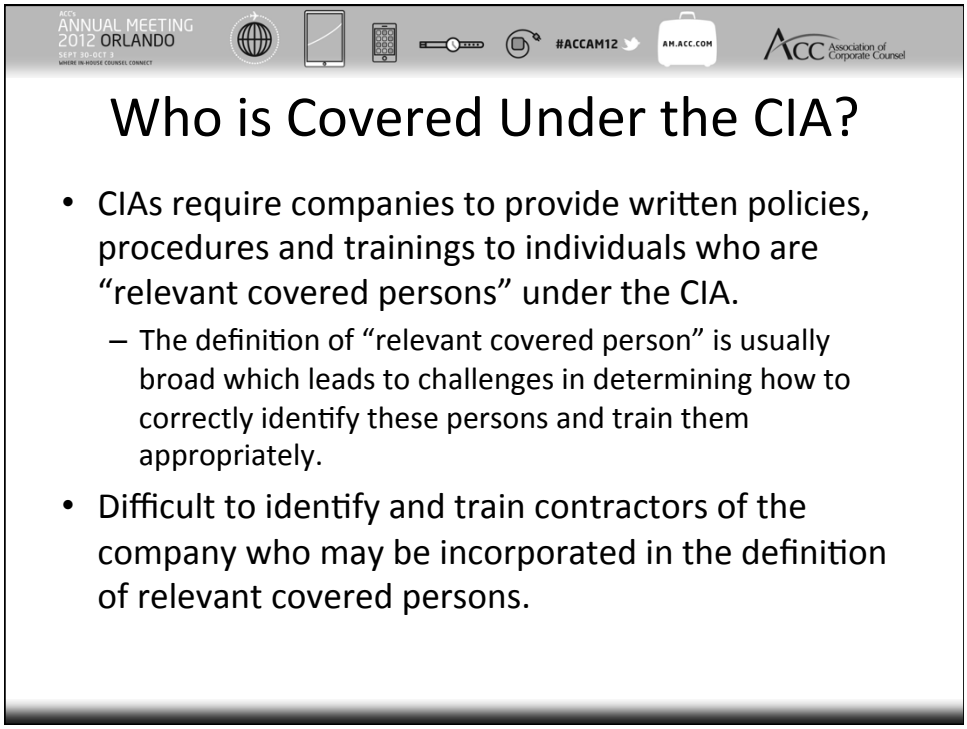
- Corporate Integrity Agreement (CIA) between OIG and health care provider or other entities as part of a settlement arising from a variety of civil false claims allegations.
- OIG agrees not to seek to exclude the other party from participation in Medicare, Medicaid, or other federal health care programs.

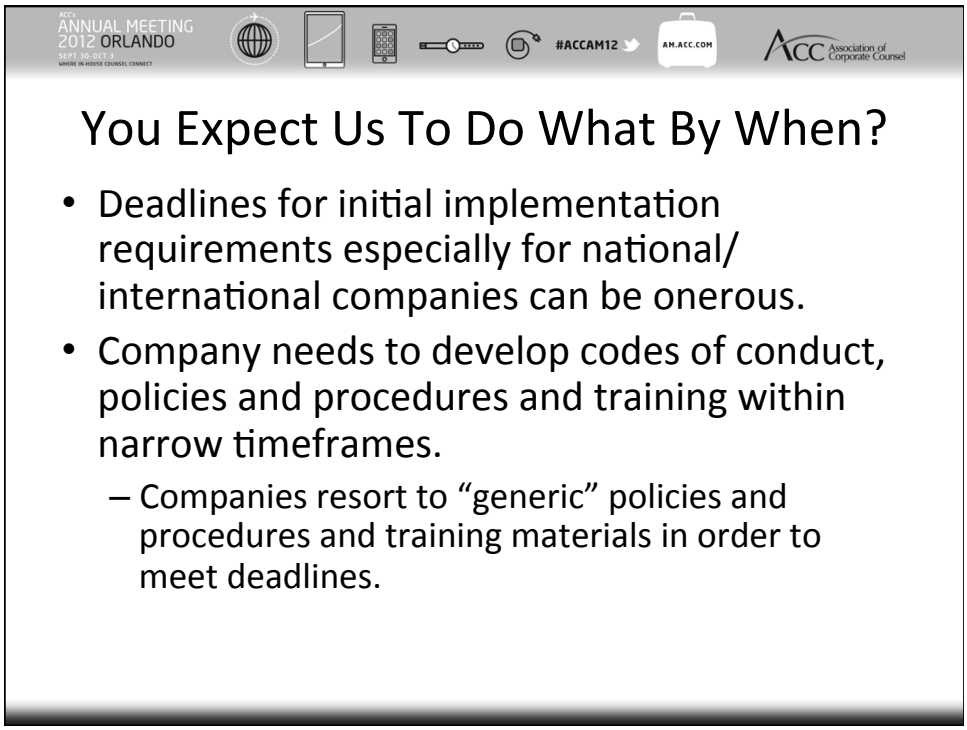
Background (cont'd)

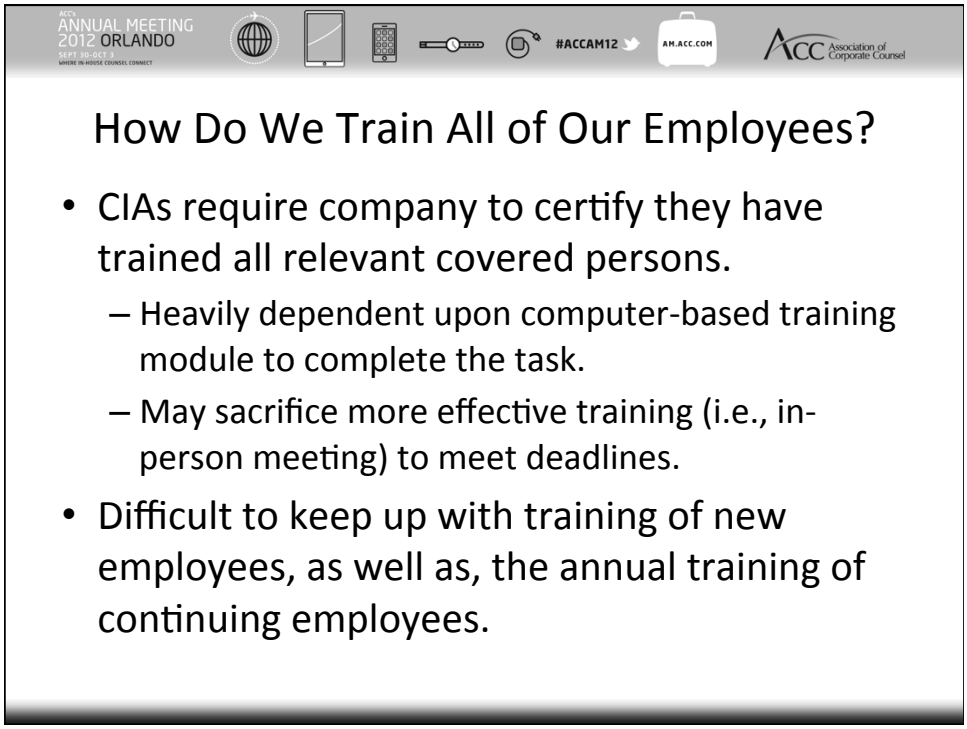
- CIAs have common elements but address the specific conduct at issue and incorporate elements of pre-existing, voluntary compliance programs.
- Typical term of a CIA is five years.

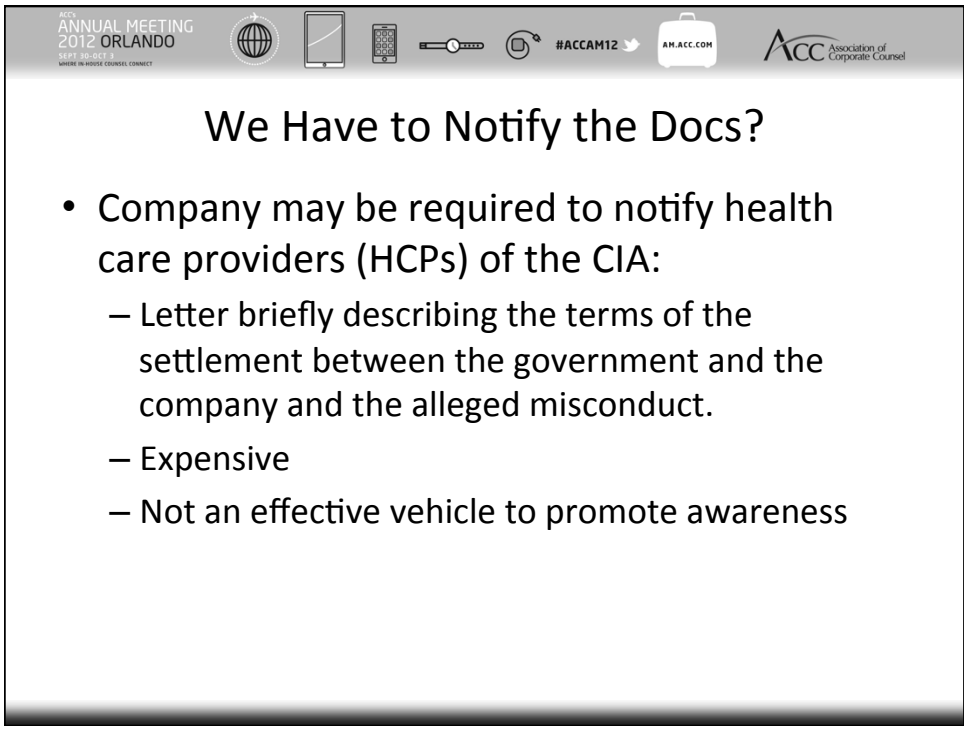


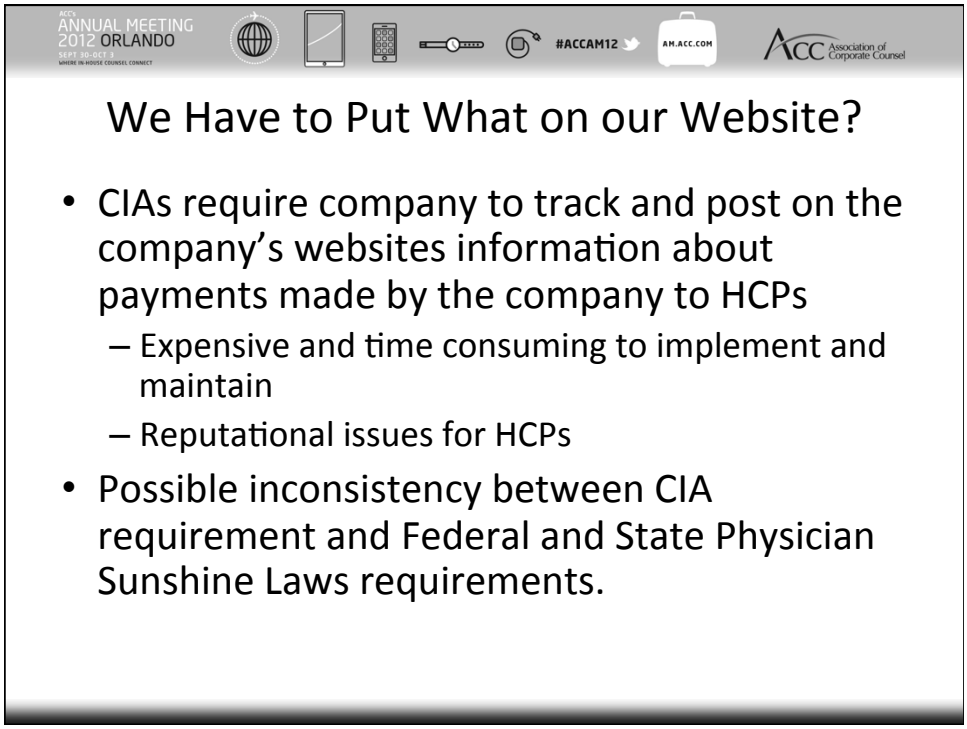


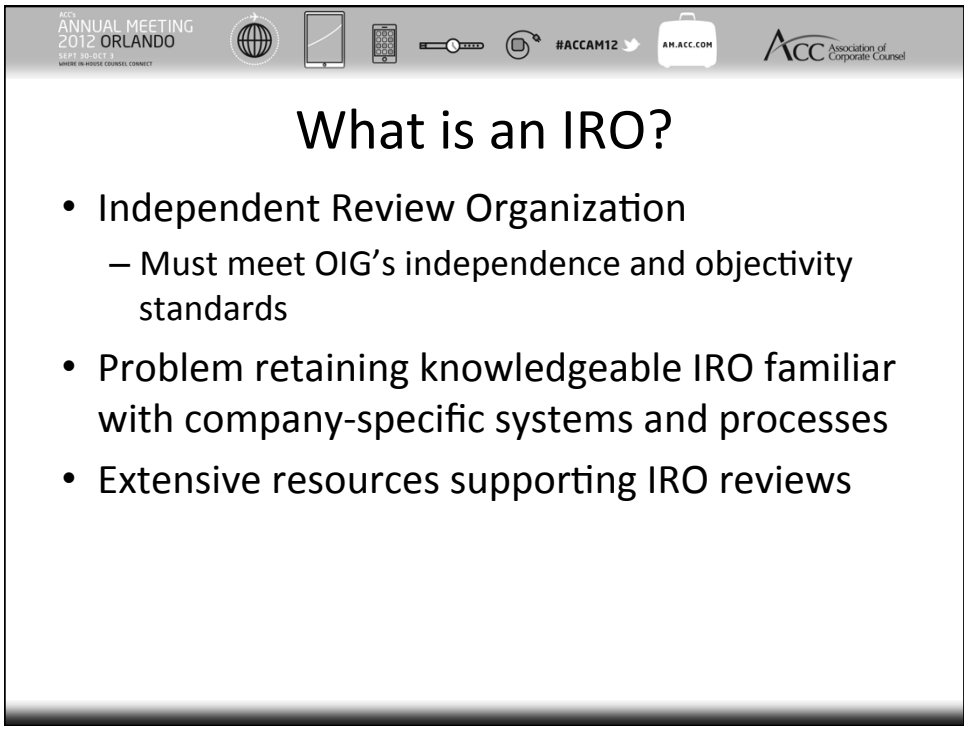


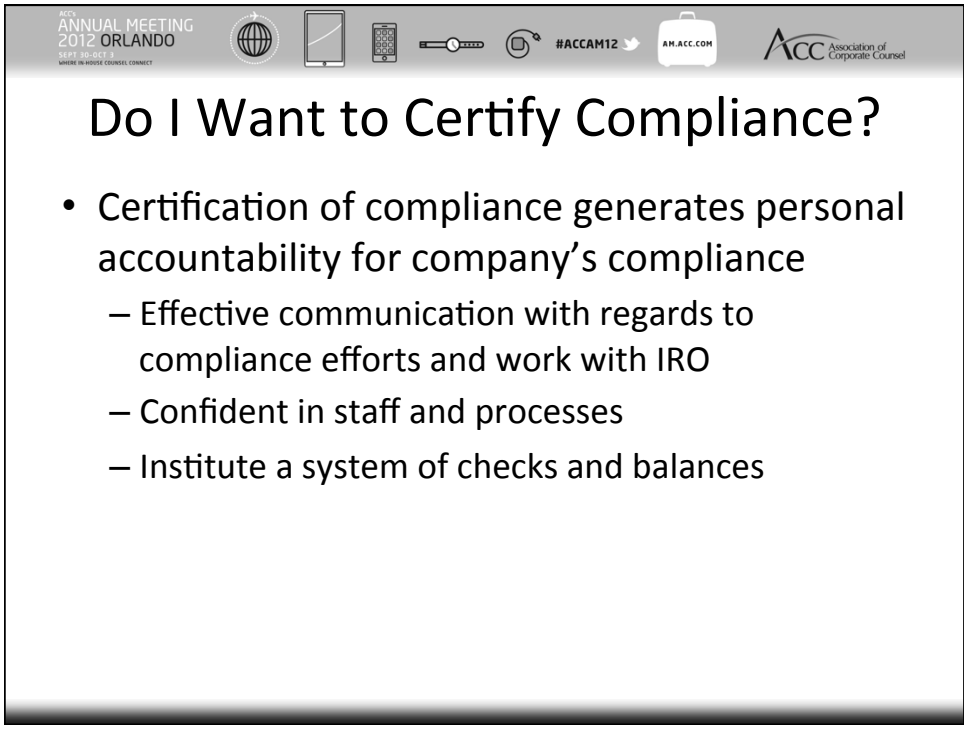


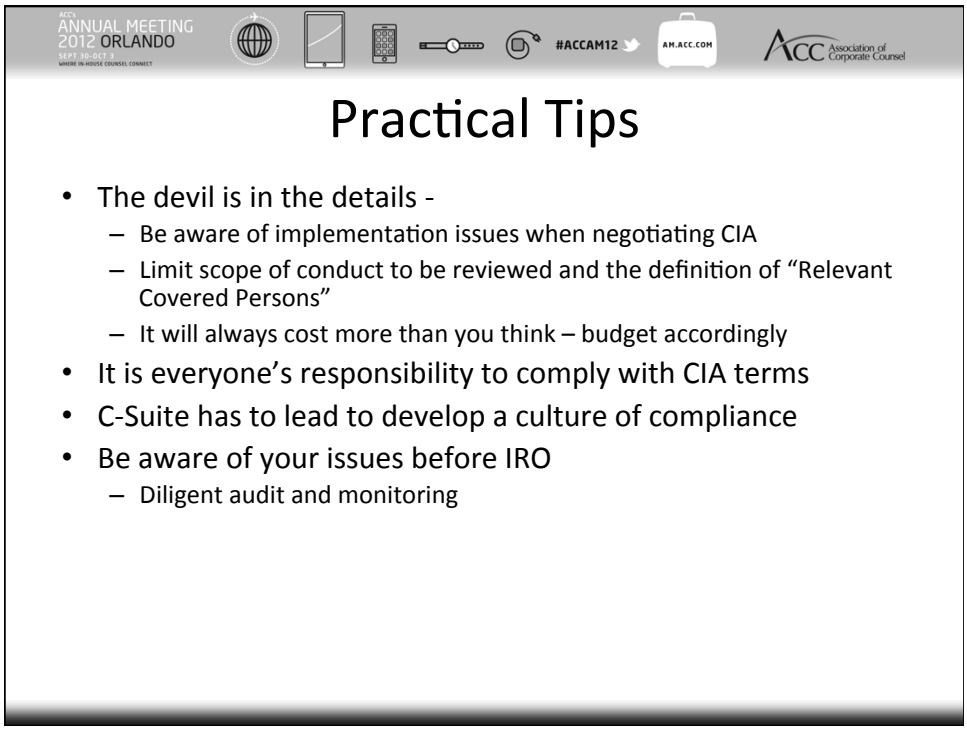


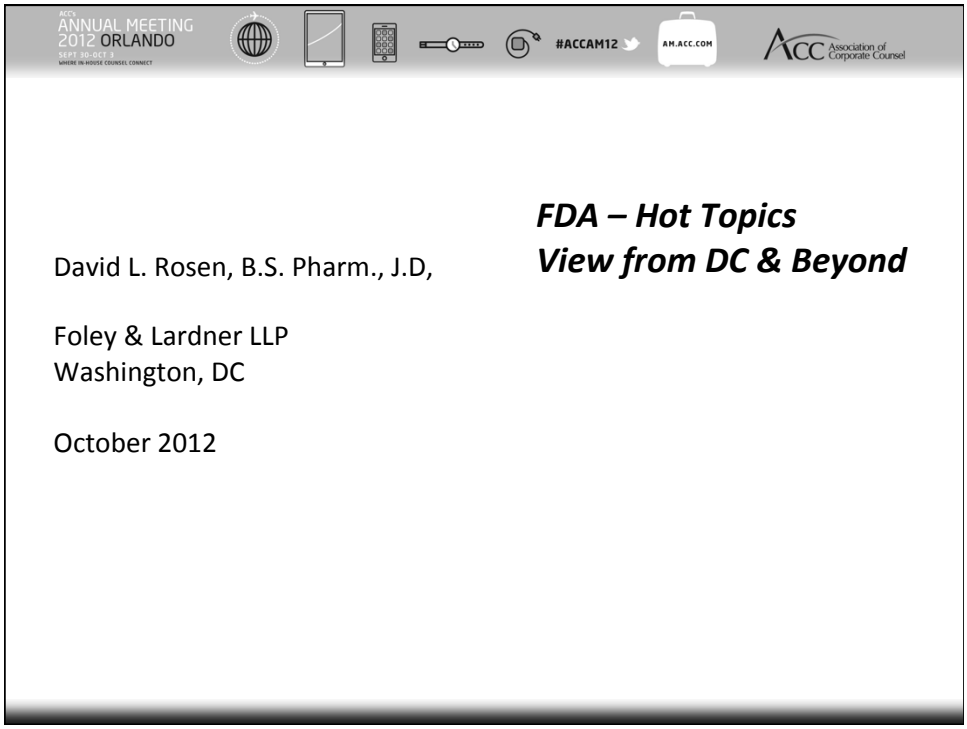


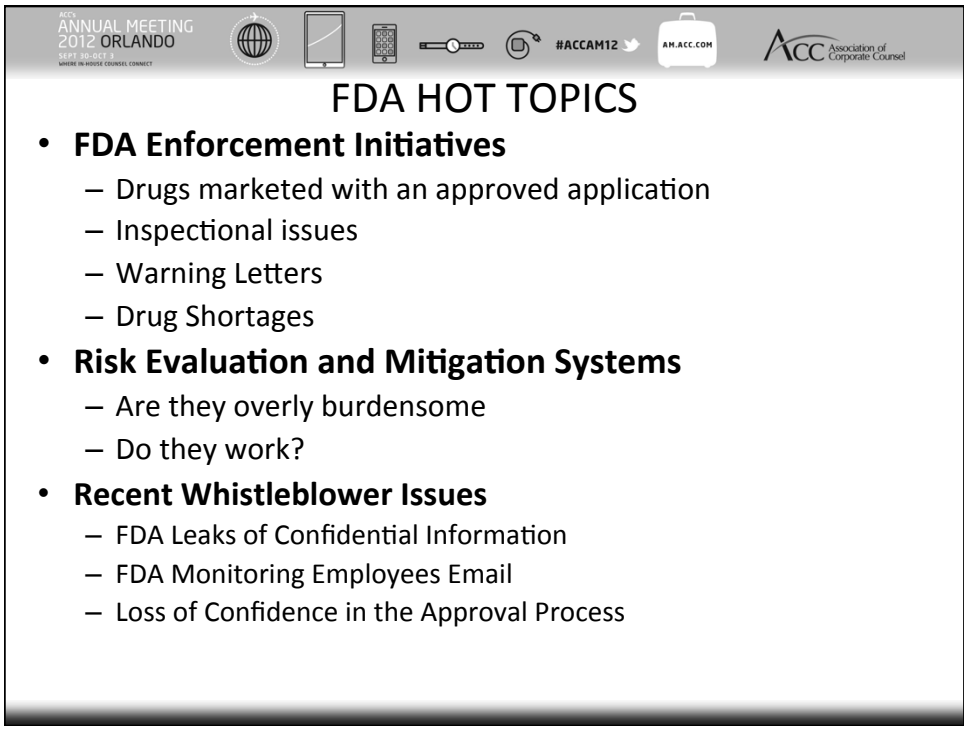












ACC's ANNUAL MEETING 2012 ORLANDO SEPT 30-OCT 3 WHERE IN-HOUSE COUNSEL CONNECT #ACCAM12 AM.ACC.COM ACC Association of Corporate Counsel

FDA Hot Topics

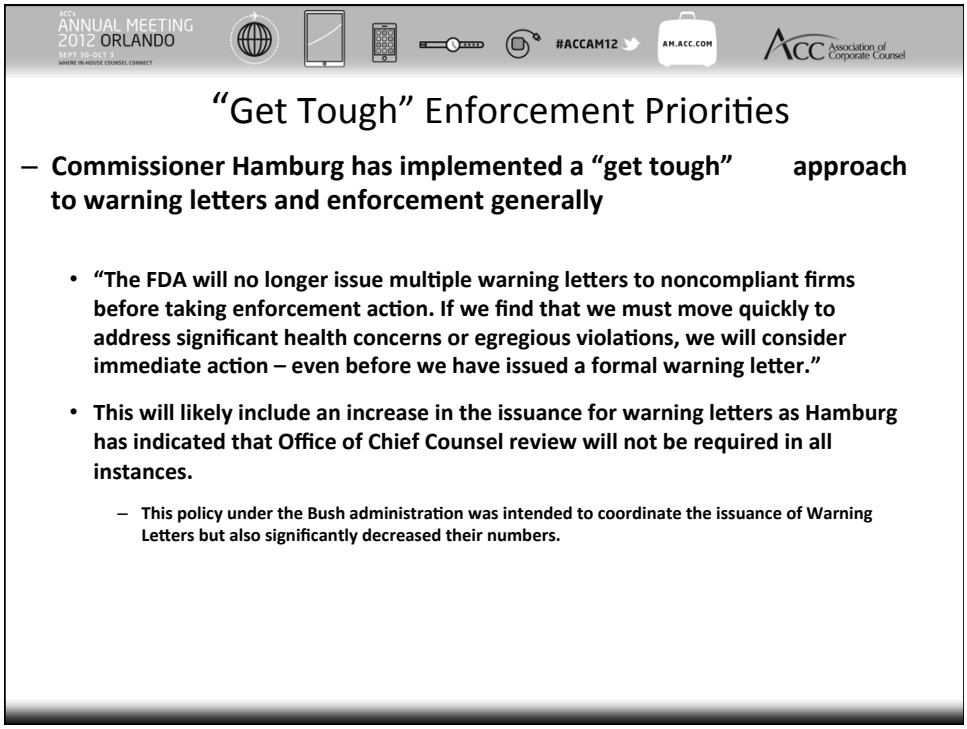
- **Generic Drug Issues**
  - Backlog
  - New Director for OGD finally on board
  - Generic Drug User Fees
  - Patent Settlement Agreements
  - Citizen Petition Responses
  - Questions about interchangeability and quality of anti-epileptic drugs
- **Biosimilars – where are we now**
  - Use fee for pre-IND meetings
  - Guidance on biosimilarity, conduct of trials, immunogenicity
  - Nomenclature
  - Interchangeability

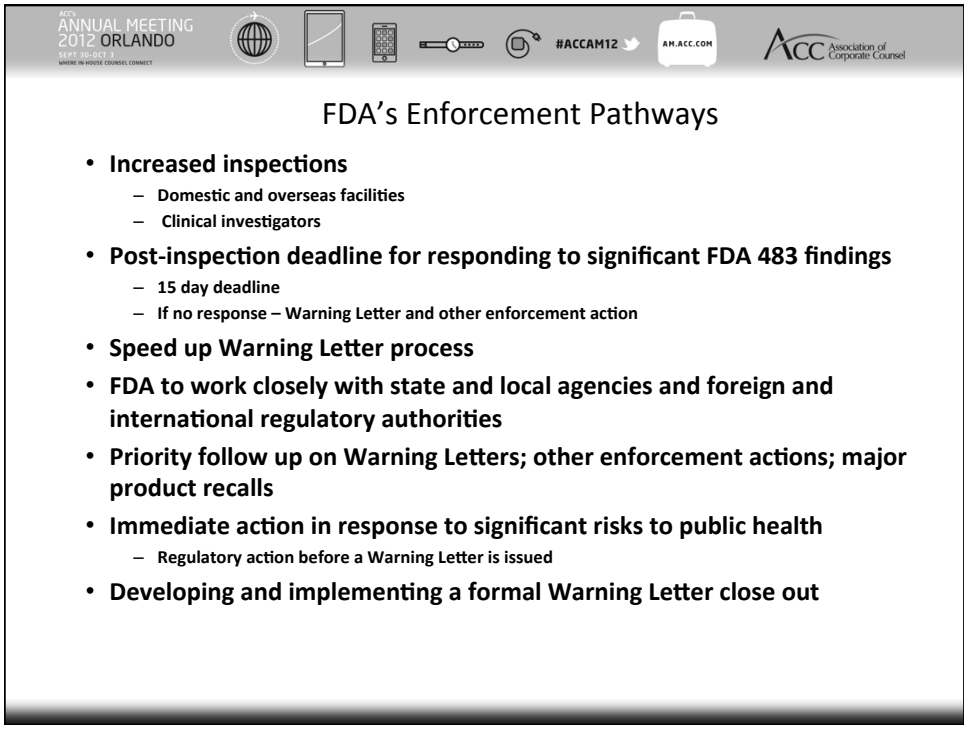
ACC's ANNUAL MEETING 2012 ORLANDO SEPT 30-OCT 3 WHERE IN-HOUSE COUNSEL CONNECT #ACCAM12 AM.ACC.COM ACC Association of Corporate Counsel

FDA Is Stepping Up Enforcement

- **The Obama Administration is sending a message to the industry – be forewarned - FDA is being much more aggressive**

FDA's Cops Are Out In Force





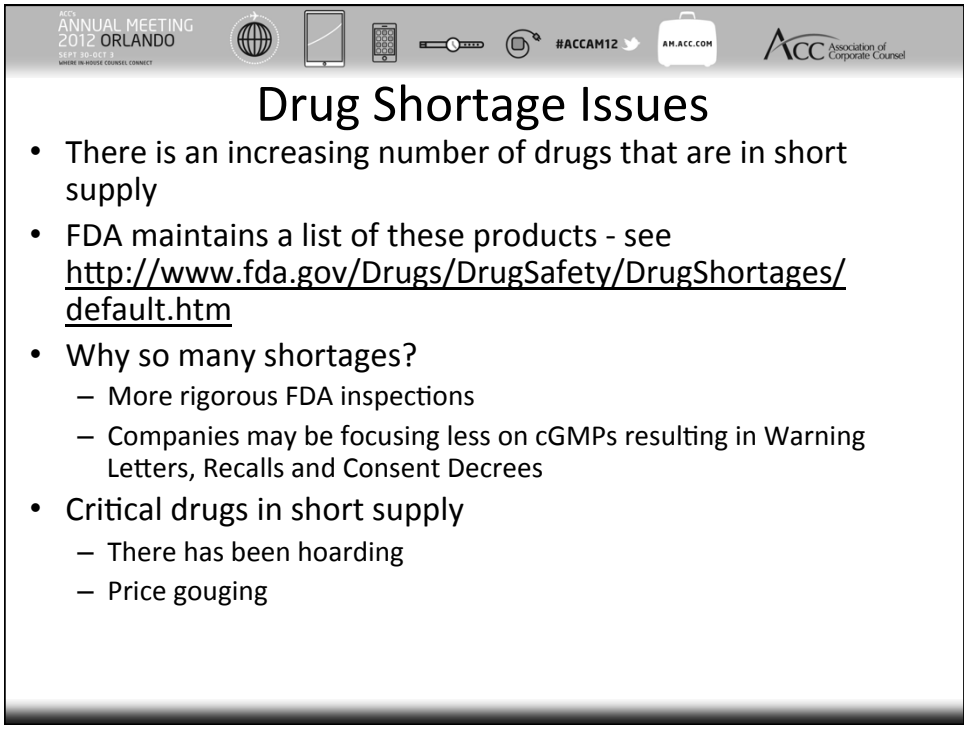
Sanctions and Penalties for Violations of the FD&C Act

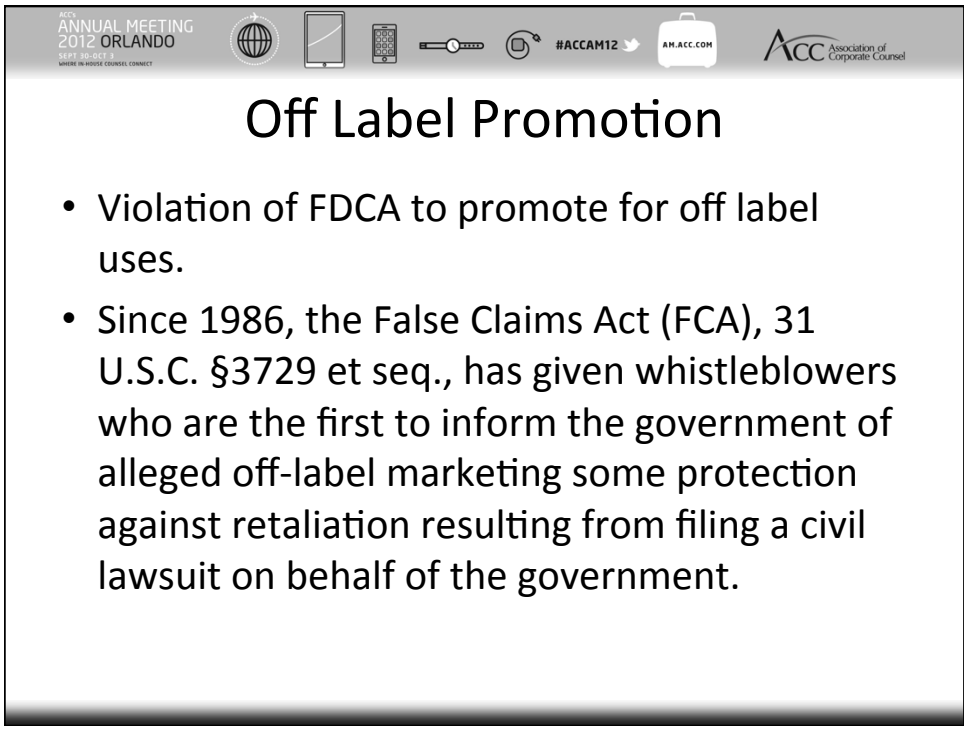
- **Regulatory Enforcement Action**
  - **Warning Letter**
  - **Import Detention**
  - **Seizure**
  - **Injunction**
- **Civil Monetary Penalties**
- **Criminal Liability**

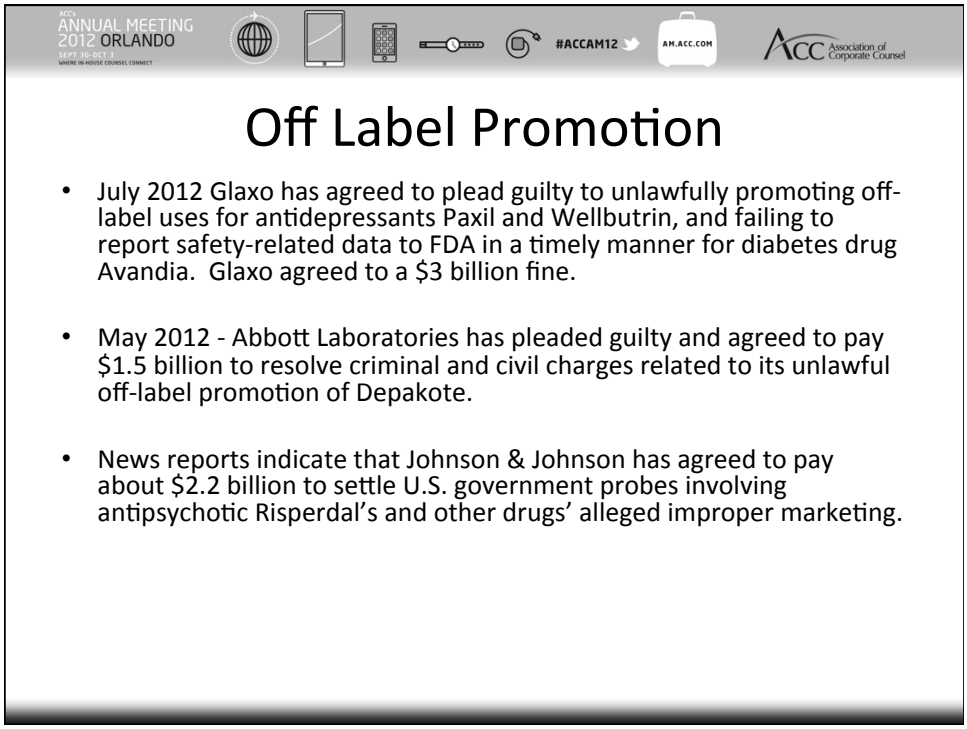
ANNUAL MEETING 2012 ORLANDO #ACCAM12 AM.ACC.COM ACC Association of Corporate Counsel

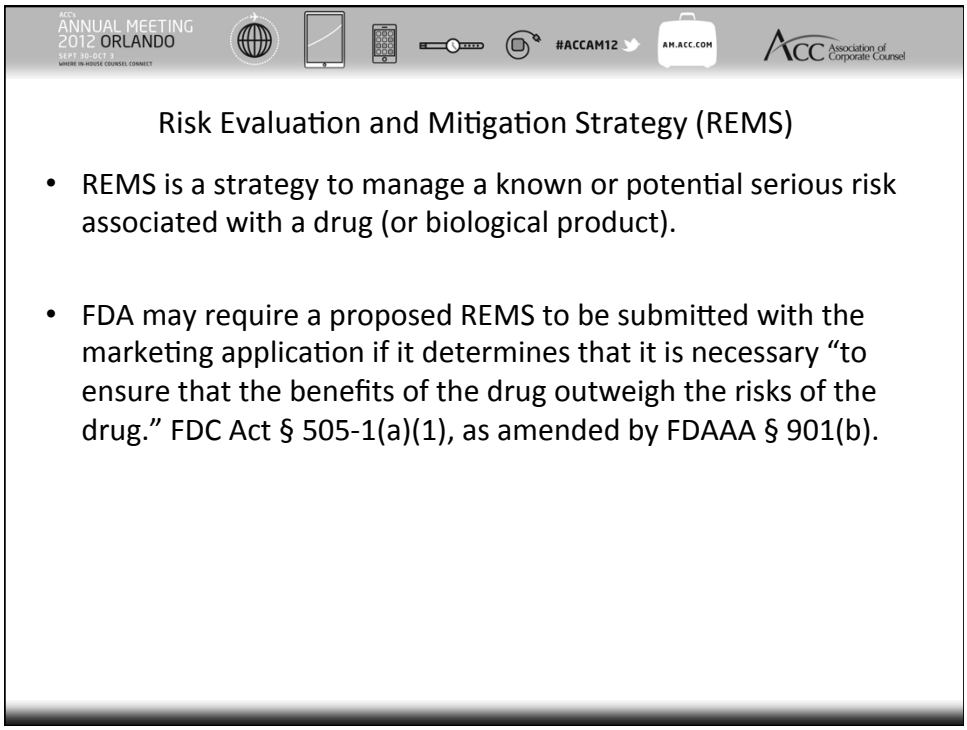
Use of the Park Doctrine

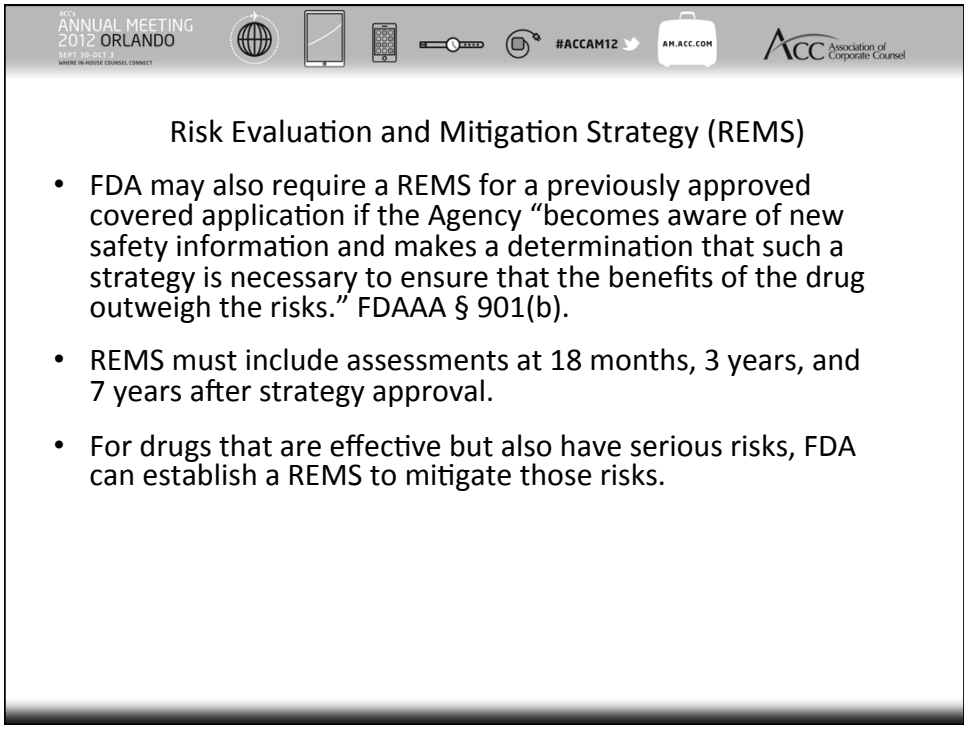
- FDA Commissioner, compliance officials and general counsel have targeted responsible individuals within pharma/biotech and medical devices
  - Seek to hold company management responsible for the actions of the company
  - Seek to impose criminal penalties
    - In addition to civil monetary penalties
  - Also use to debar individuals from future participation in product development and in other federal programs
- Person by reason of his/her position in the corporation, has the responsibility and authority to prevent or promptly correct a violation and fails to do so

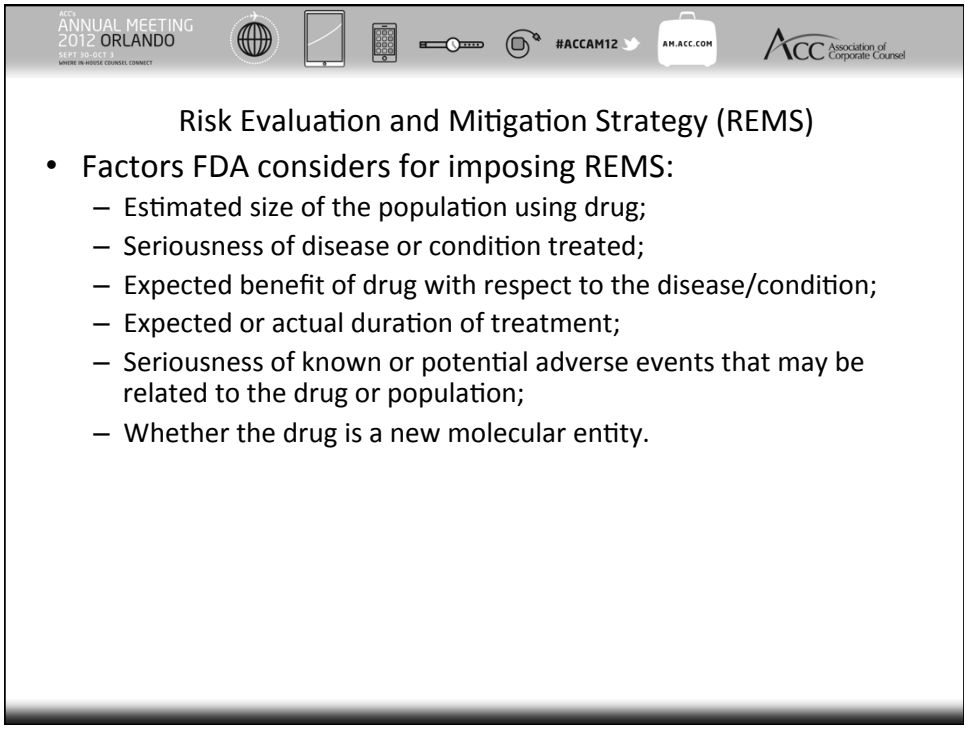


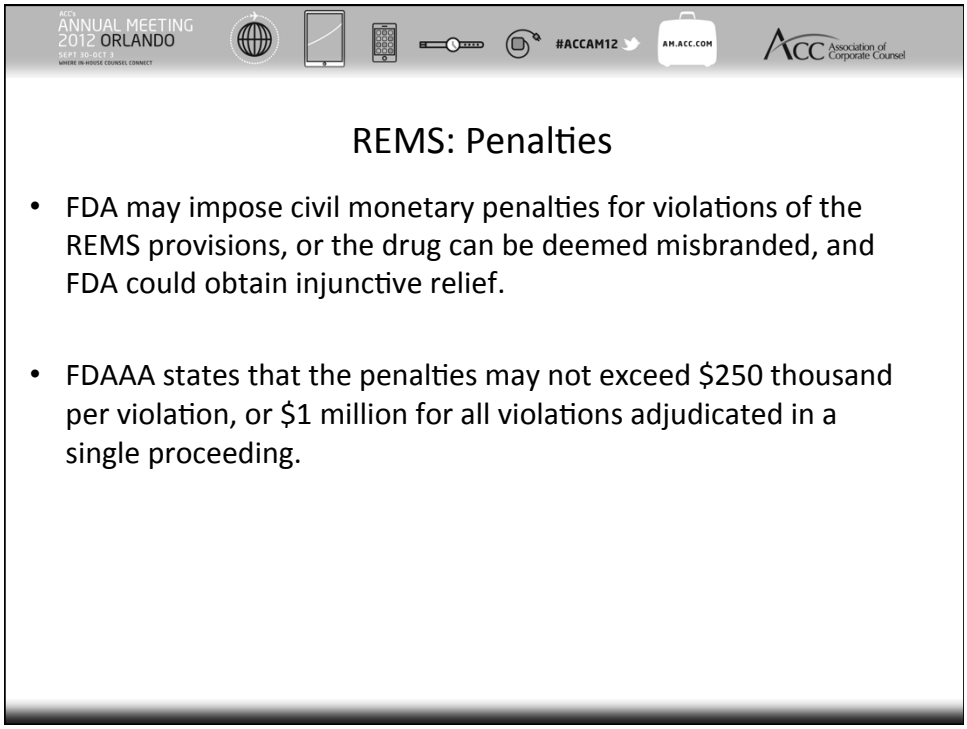


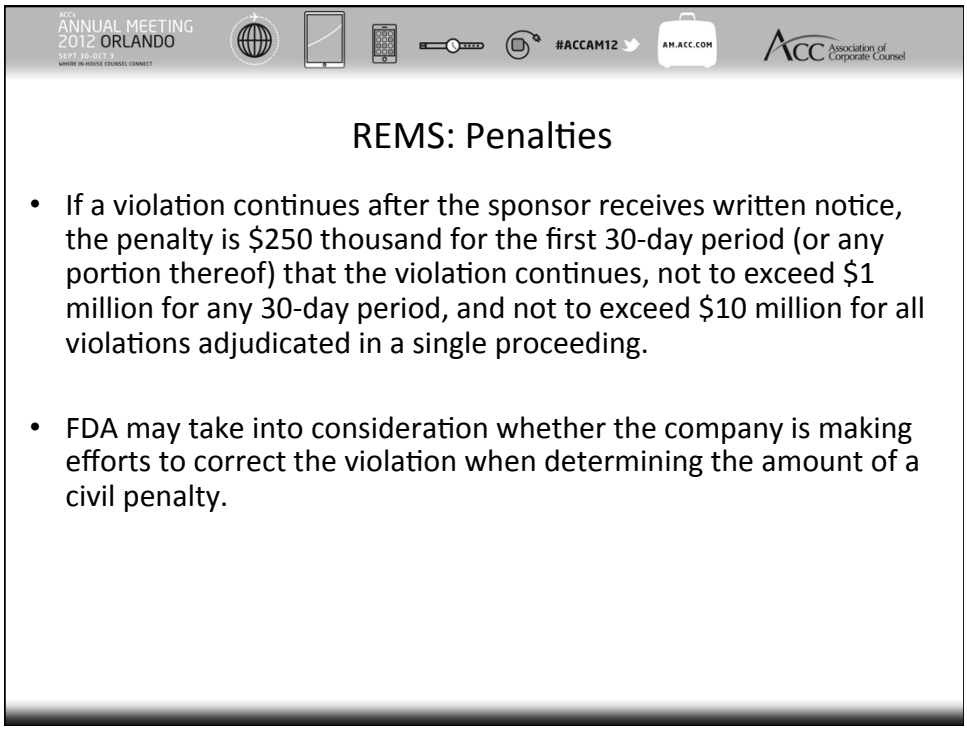


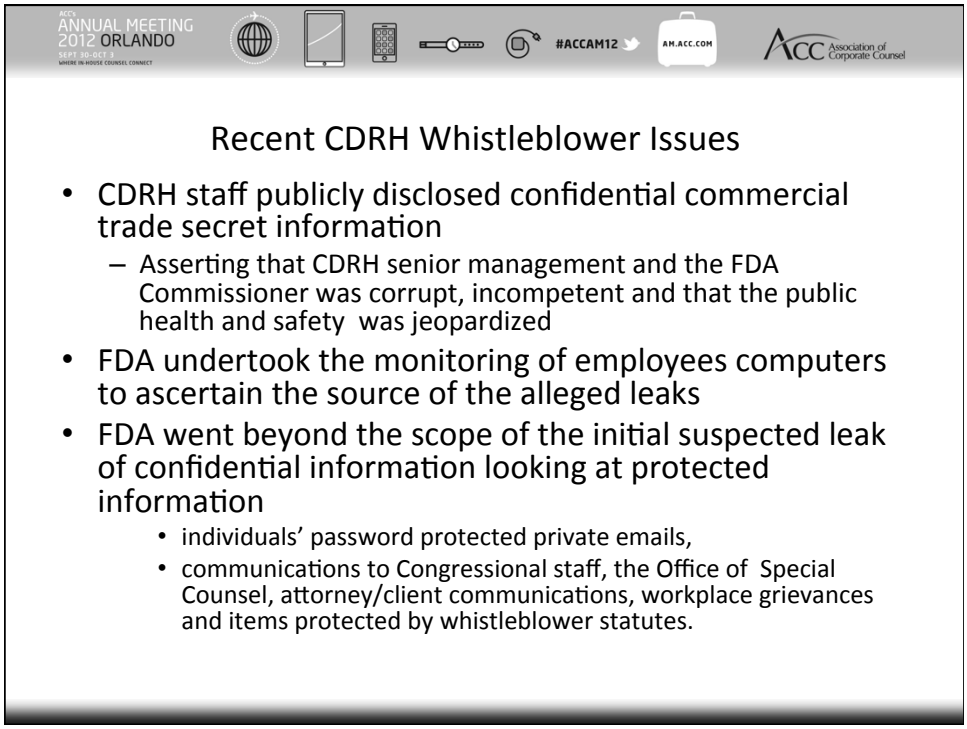


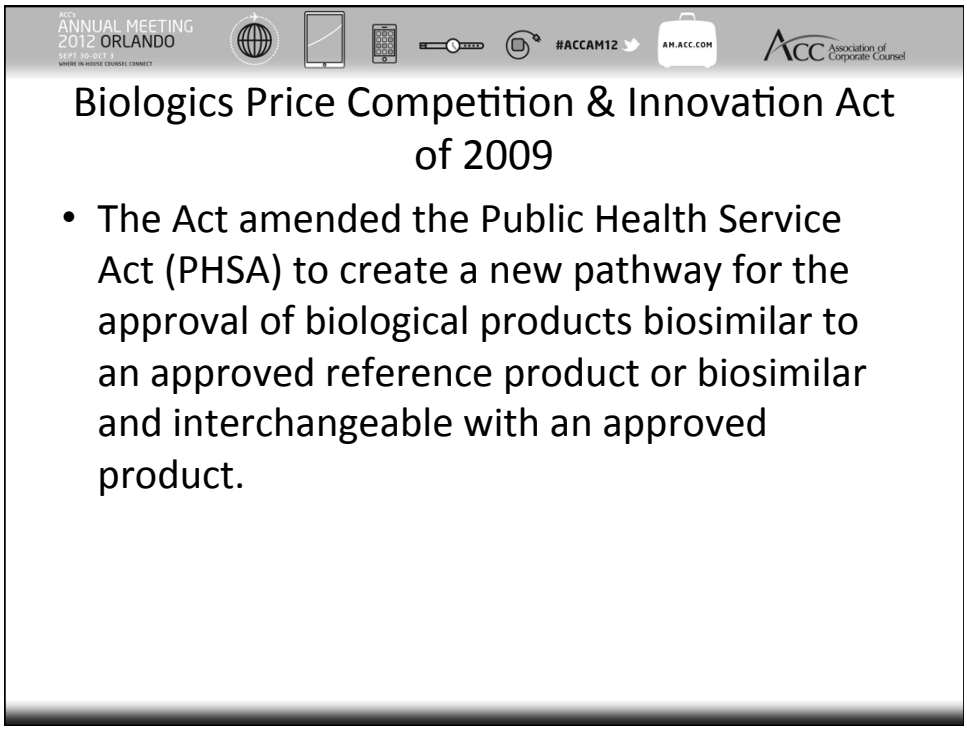


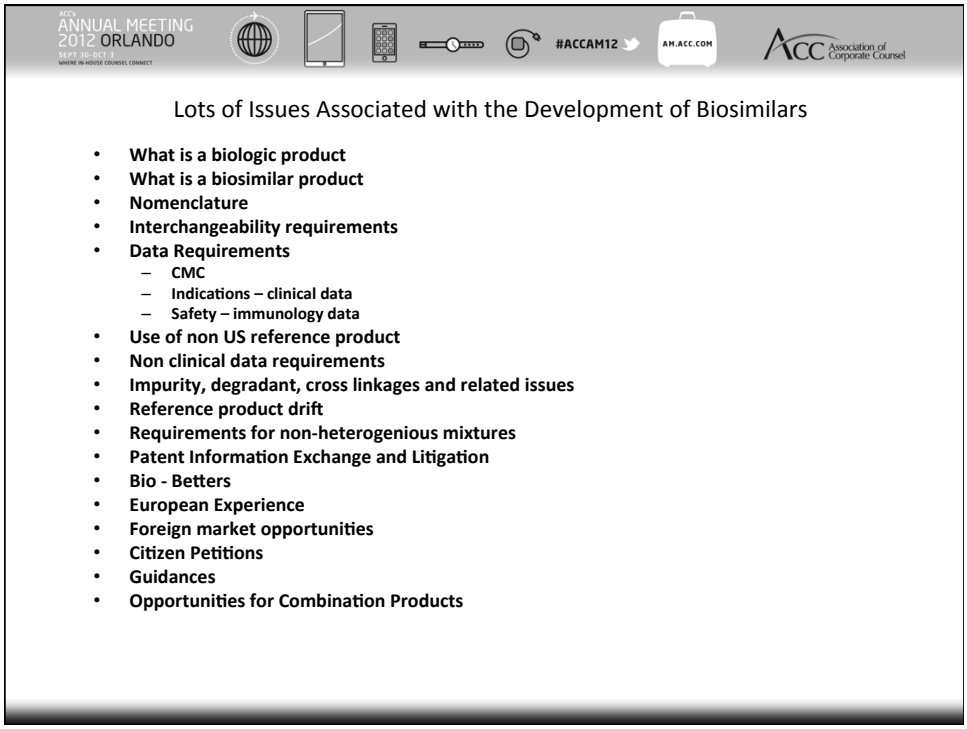


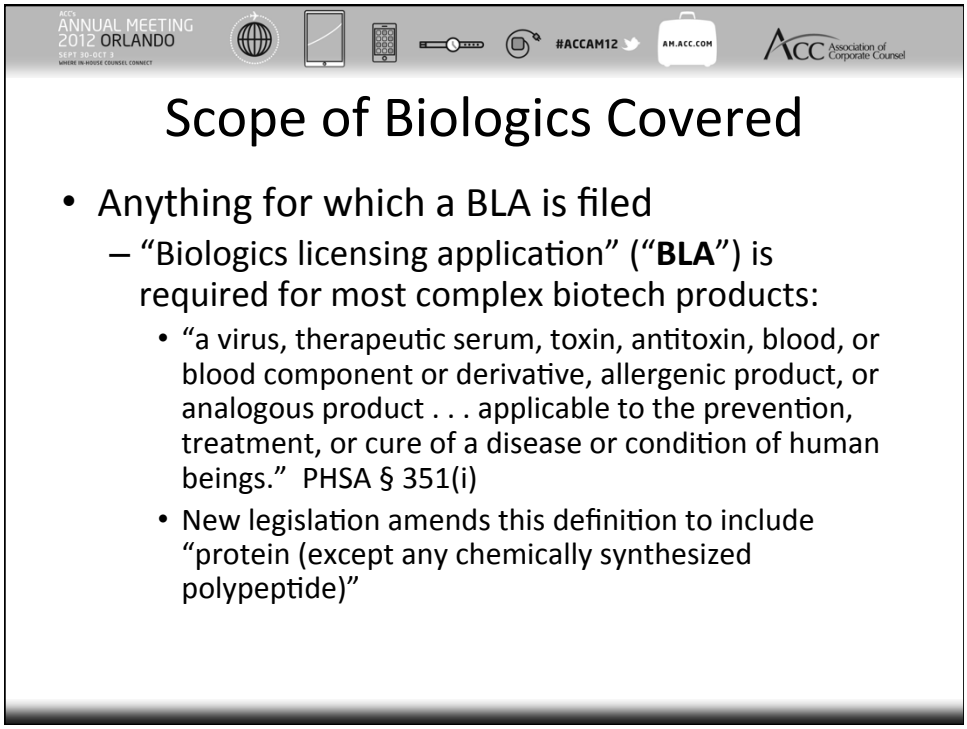


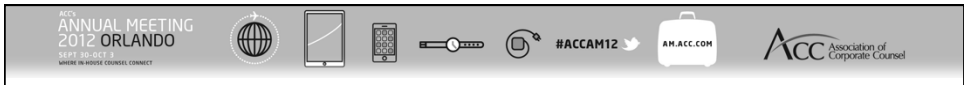






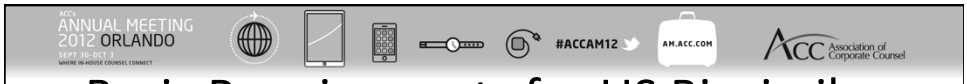






Definitions

- A "biosimilar" product is:
  - (1) highly similar to the reference product notwithstanding minor differences in clinically inactive components and
  - (2) no clinically meaningful differences in terms of safety, purity and potency.
- An "interchangeable" biosimilar is a biological product that "may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product."



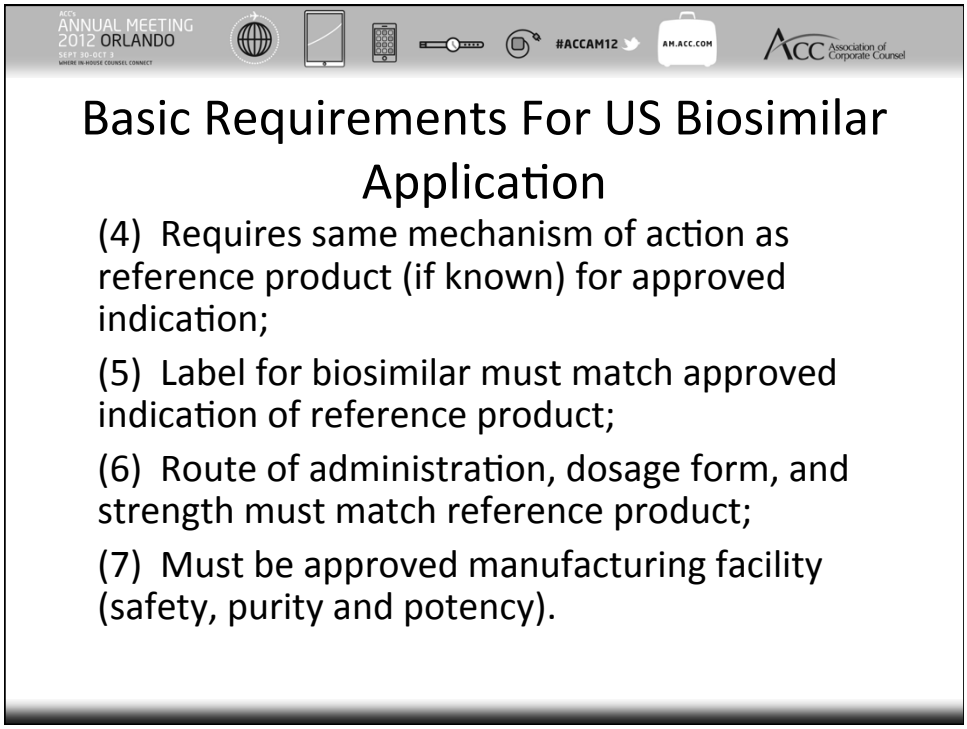
Basic Requirements for US Biosimilar Application

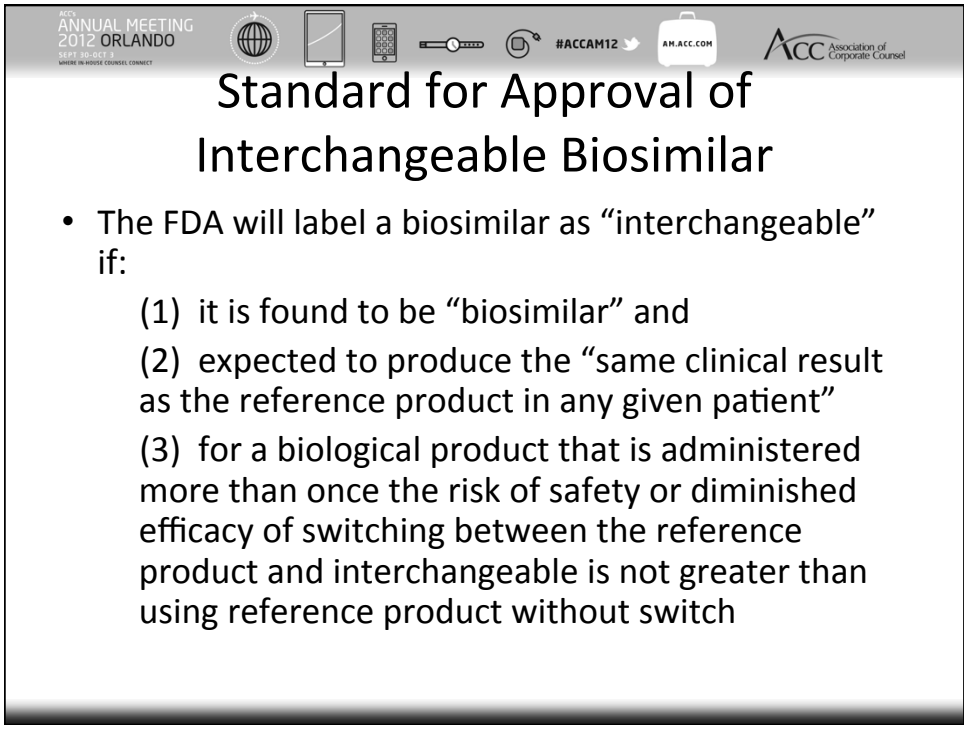
(1) Analytical studies showing product is "**highly similar**" to a reference despite "differences in clinically inactive components;"

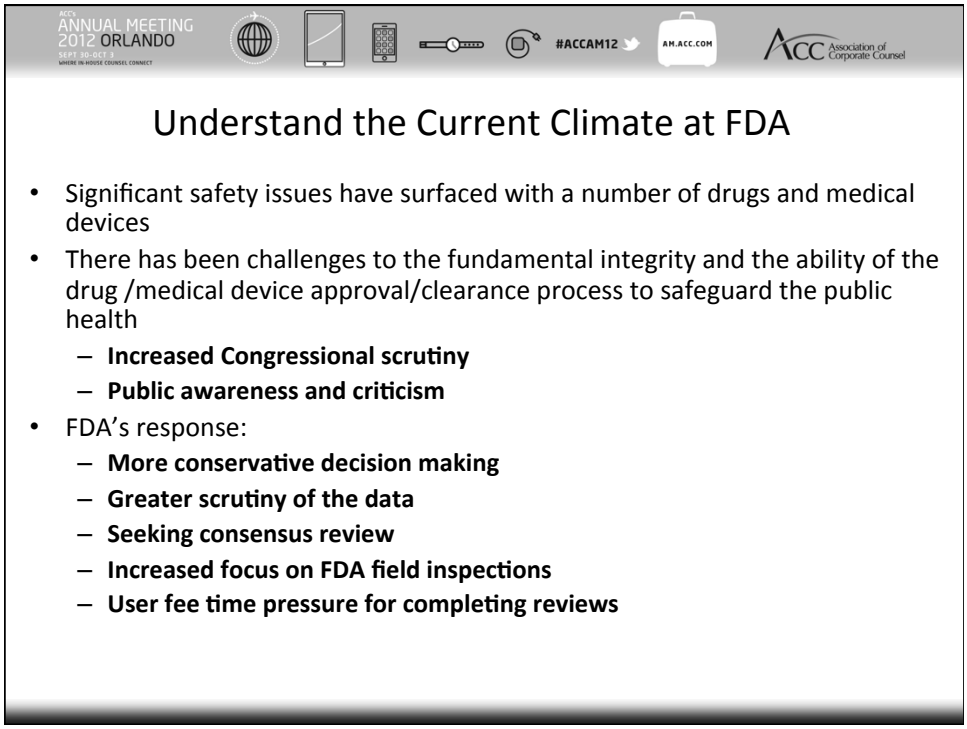
(2) Animal studies (including assessment of toxicity);

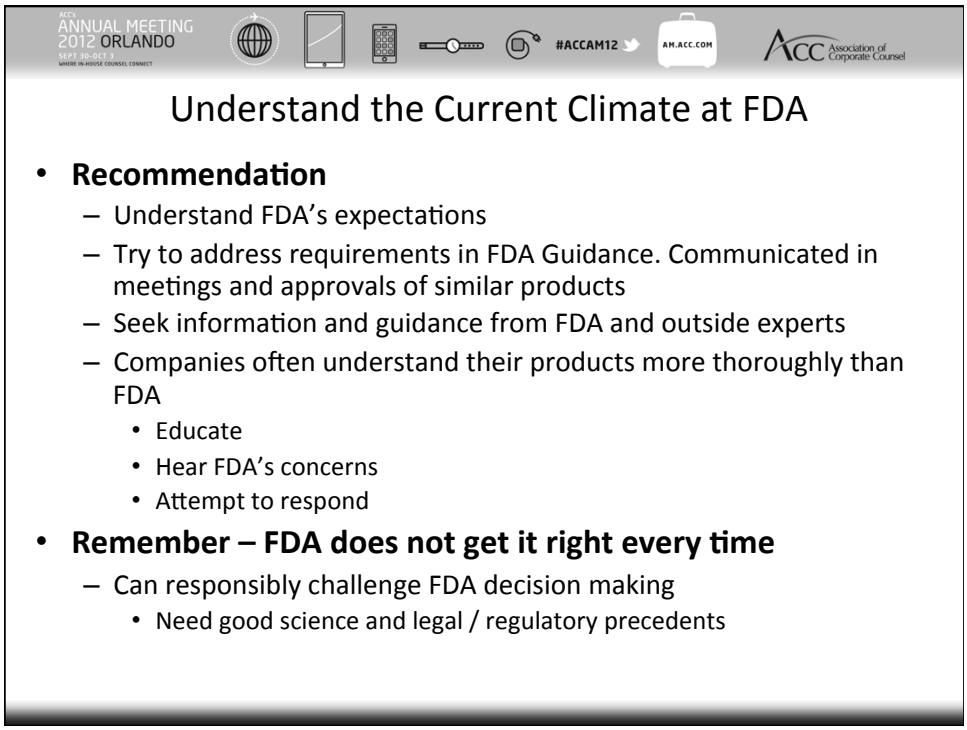
(3) Clinical study(ies) sufficient to demonstrate "safety, purity and potency in 1 or more appropriate conditions for use" that parallel an approved use of the reference product;

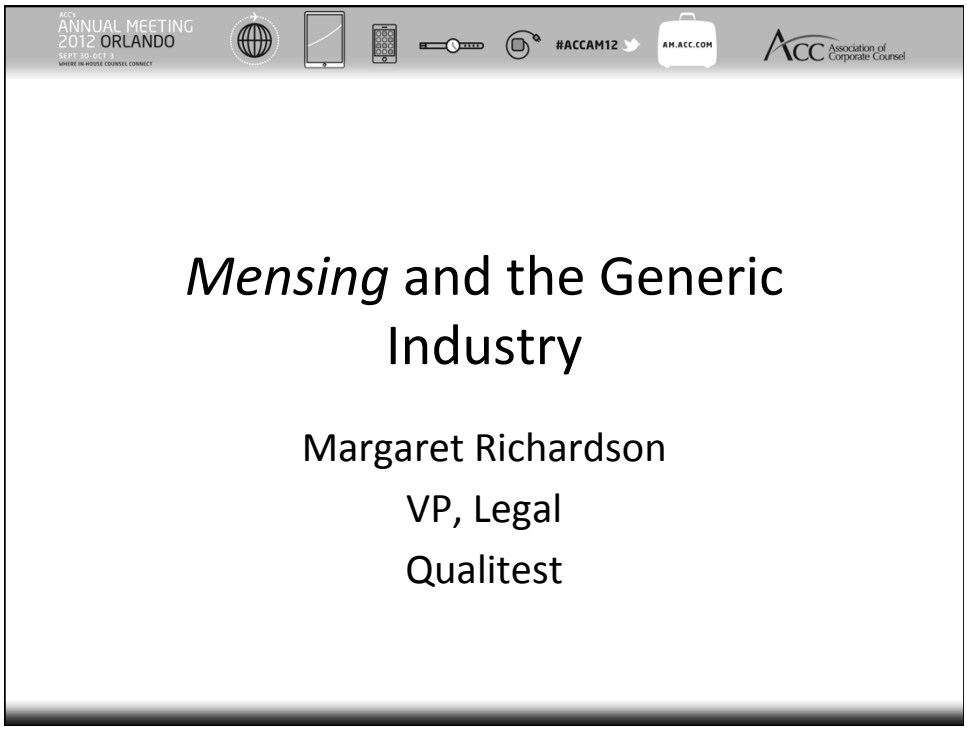
**note:* FDA may determine that any of 1-3 is not required in a given case*

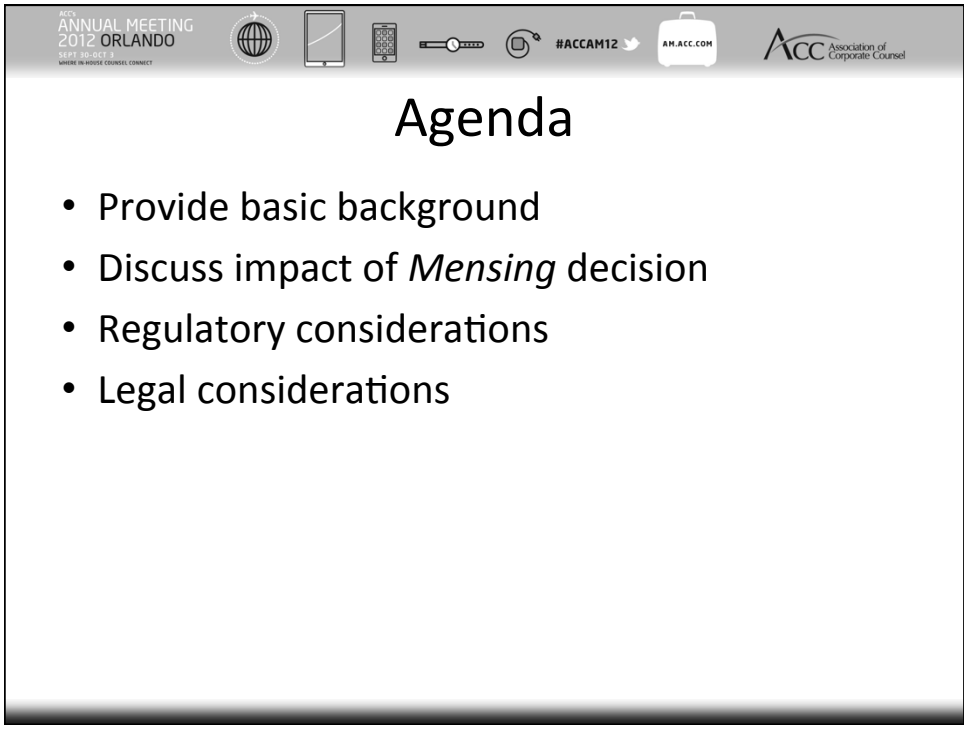


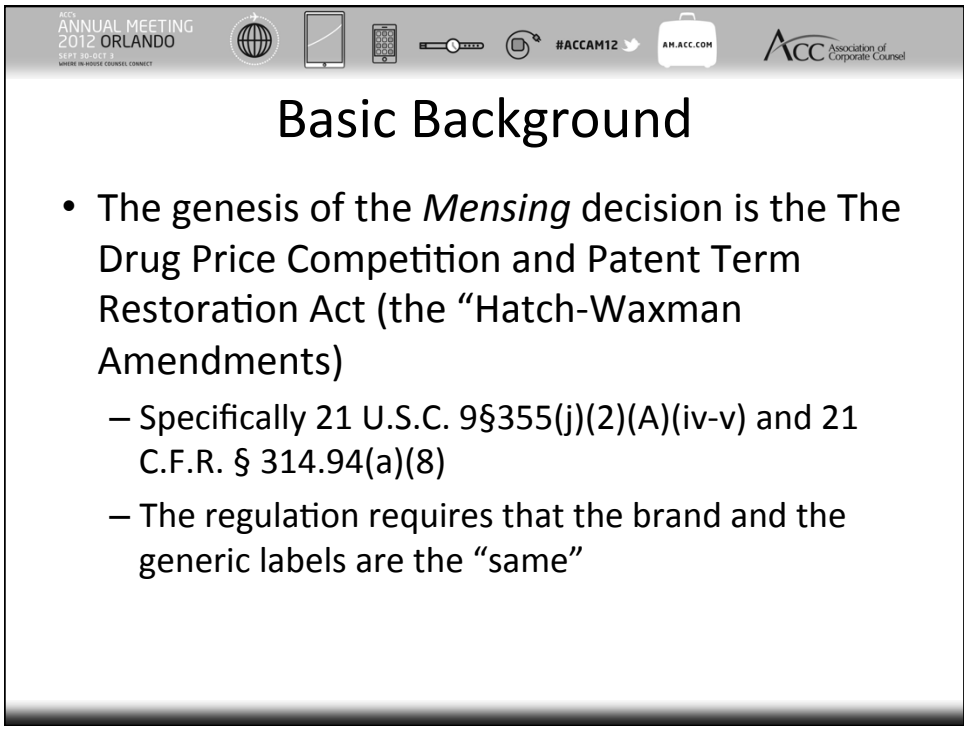


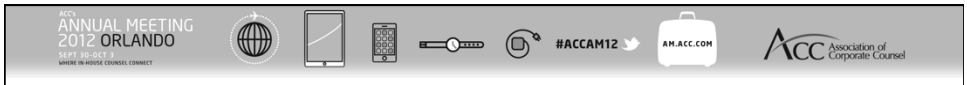






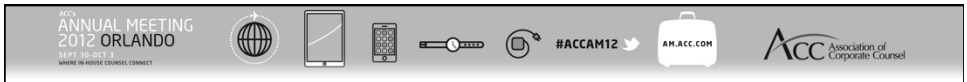






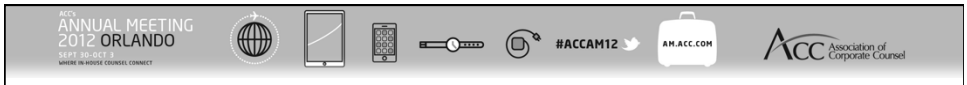
Basic Background

- The Supreme Court found in *Mensing* that by requiring the brand and generic labels to be the "same" made it impossible for generic manufacturers to update labels and therefore could not be found liable under state law for failure to warn because the federal law preempted state law and did not allow for label changes.



Impact of *Mensing*

- The immediate impact was a dismissal of several pending cases against generic manufacturers
- The secondary impact included the following:
  - Proposed legislation (S.2295, 112th Cong. (2d. Sess. 2012) titled "Patient Safety and Generic Labeling Improvement Act.")
  - Several negative news articles (New York Times "Generic Drugs Proving Resistant to Damage Suits, March 21, 2012)

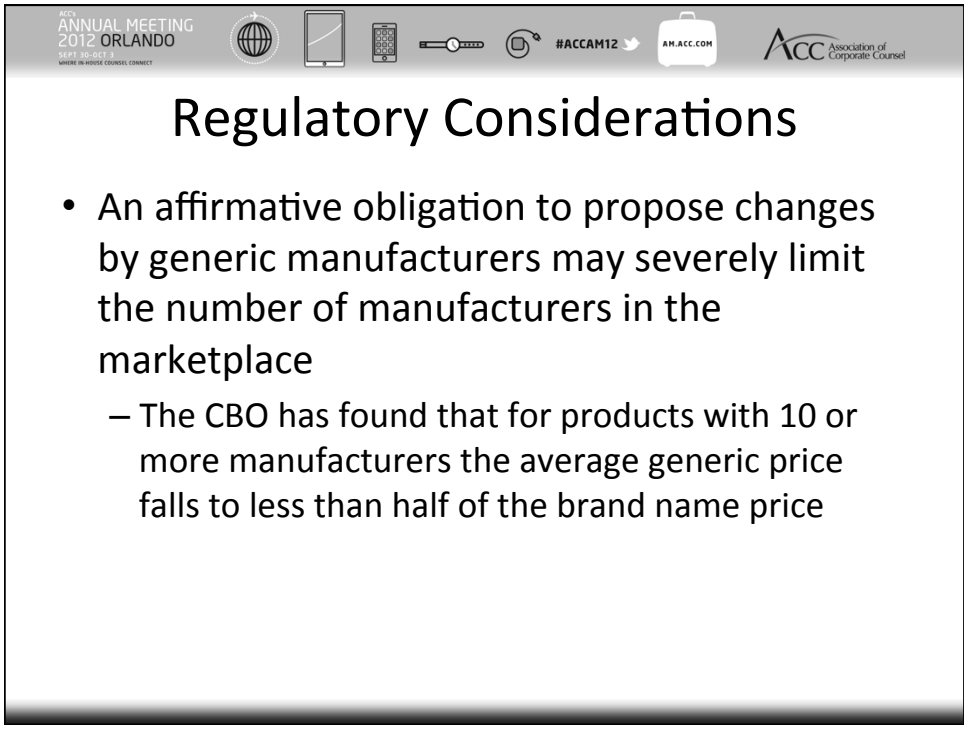


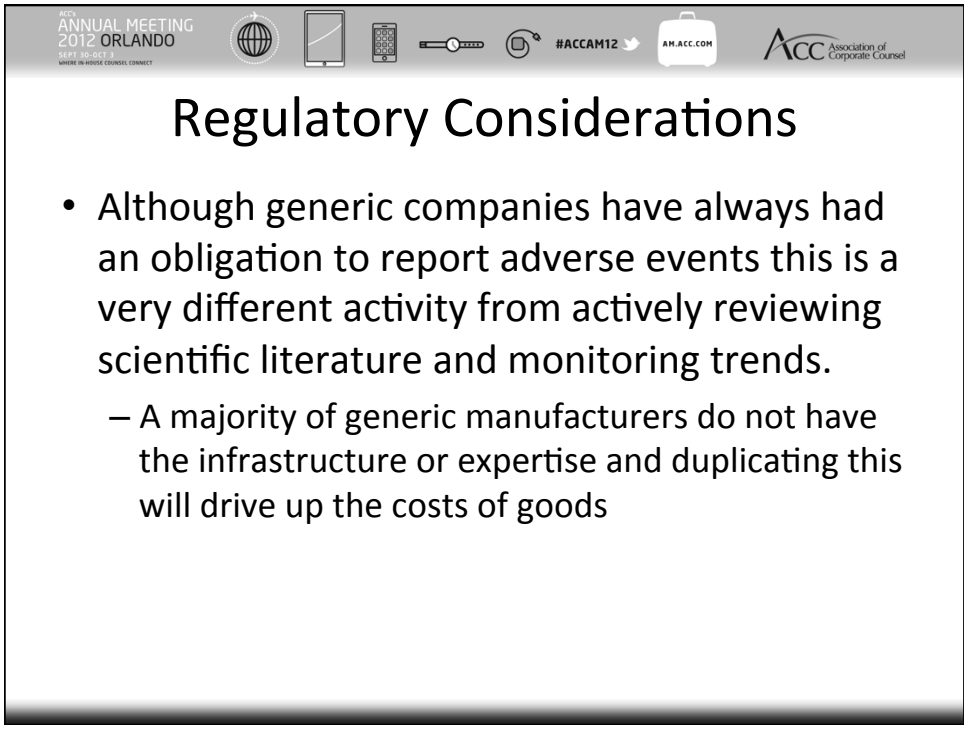
Impact of *Mensing*

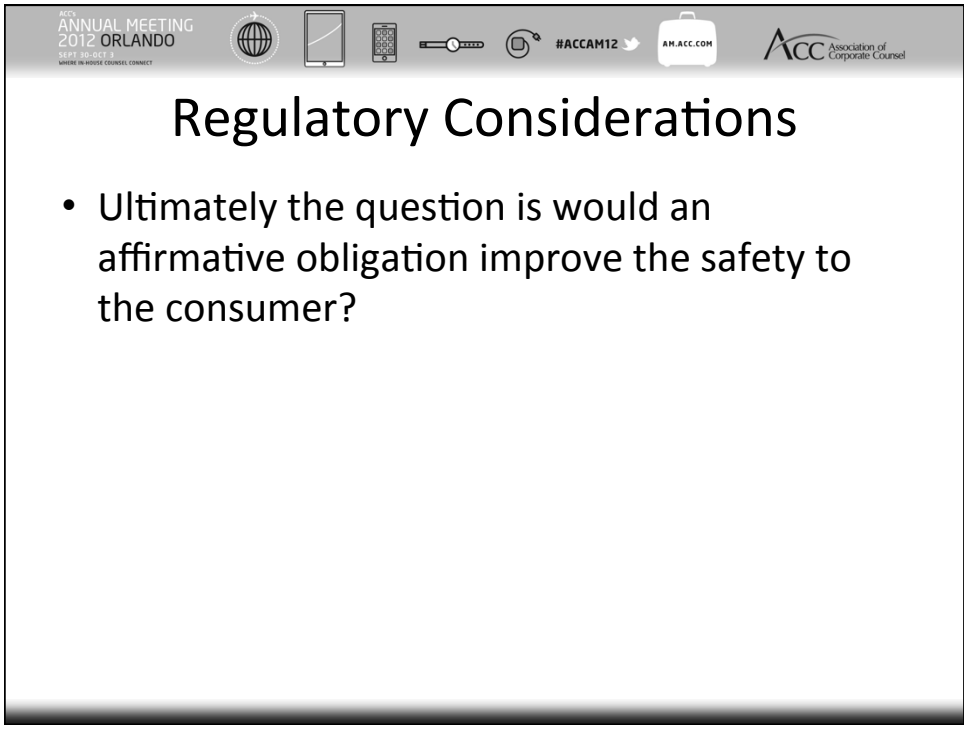
- Beyond the headlines, generic manufacturers have been actively considering options associated with increased scrutiny and the possibility that the FDA may implement new guidance that creates a process for proposed label changes by generic manufacturers.

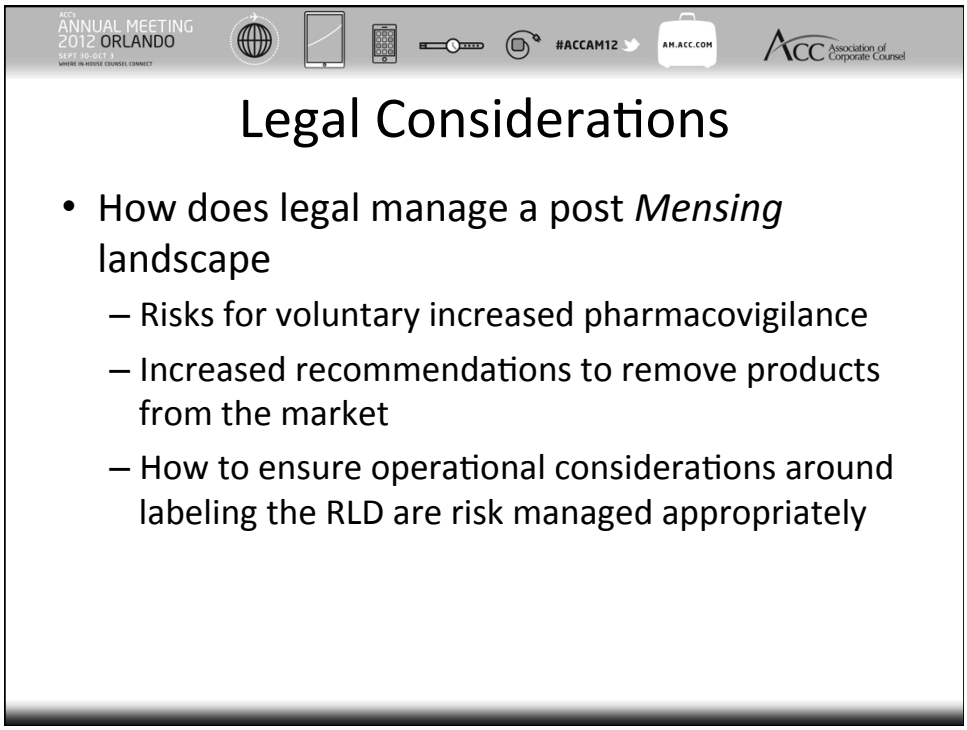
Regulatory Considerations

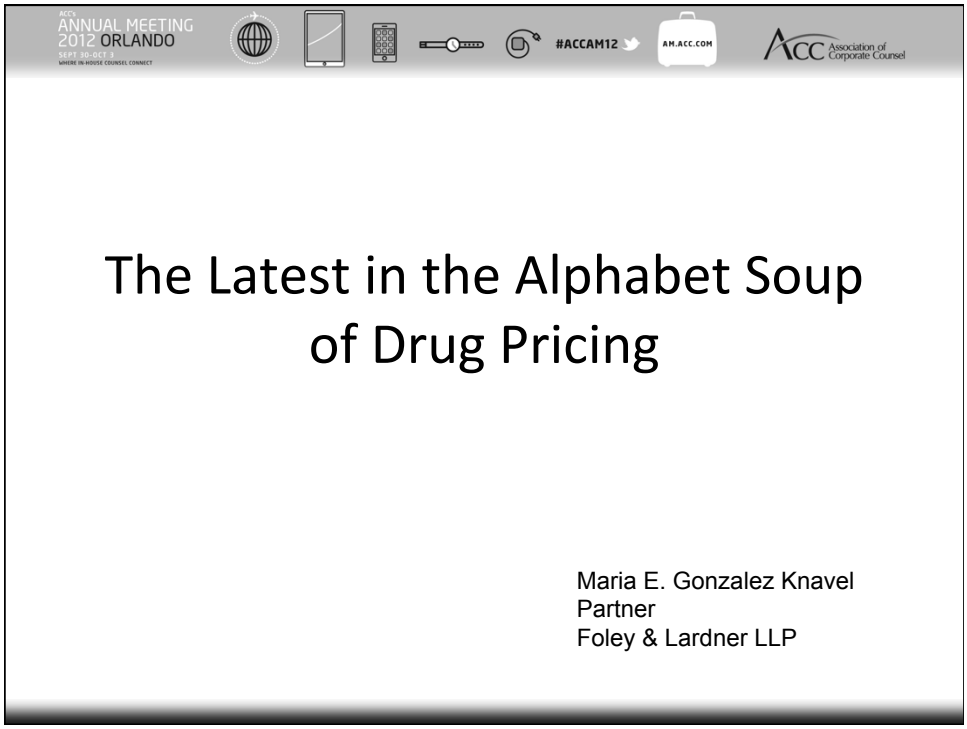
- Any proposed change to the FDA process must consider that most generic products have more than one manufacturer which is completely different from the brand setting because brand has only one manufacturer.
  - This could lead to more than one label on the market at a time and real consumer product confusion

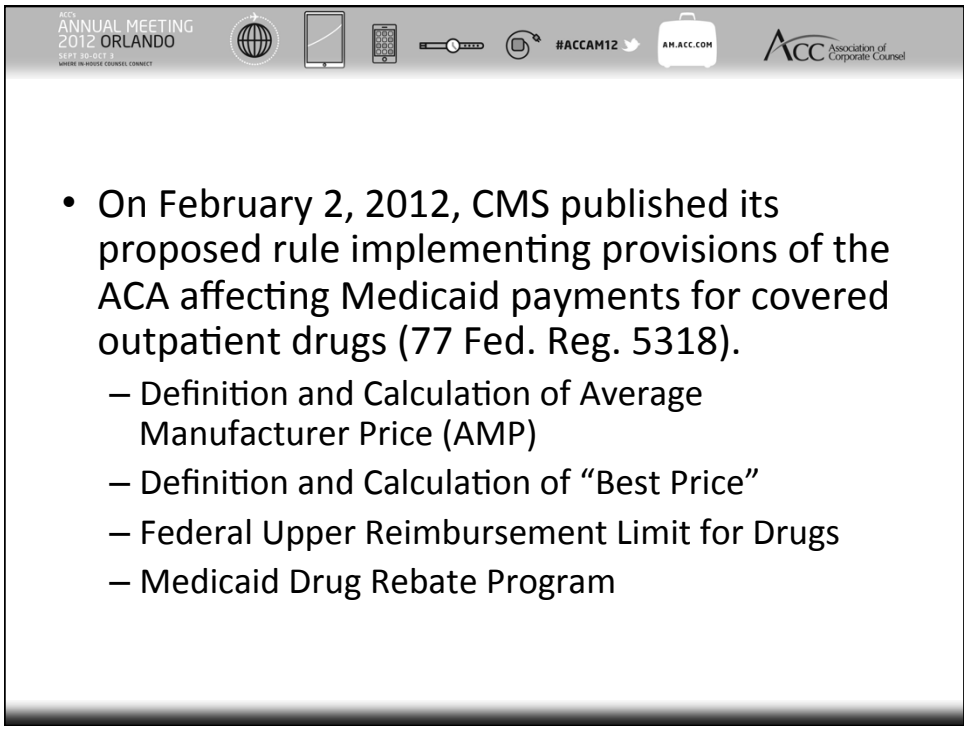


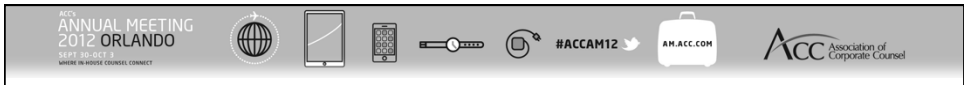




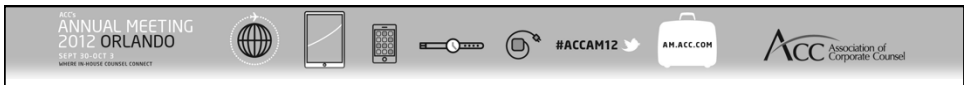






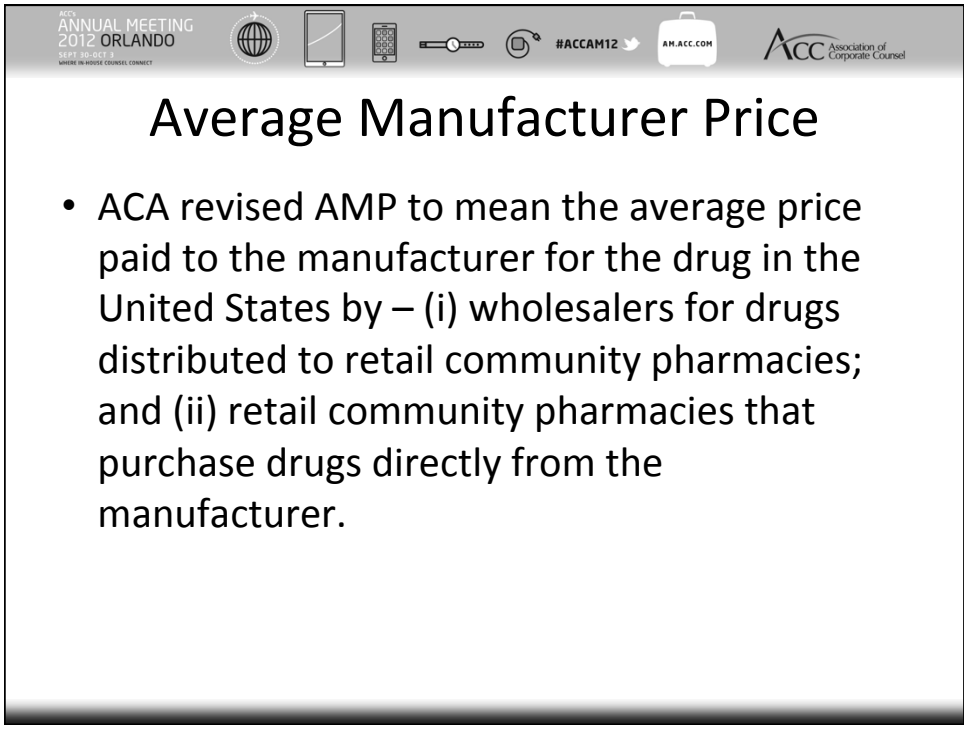


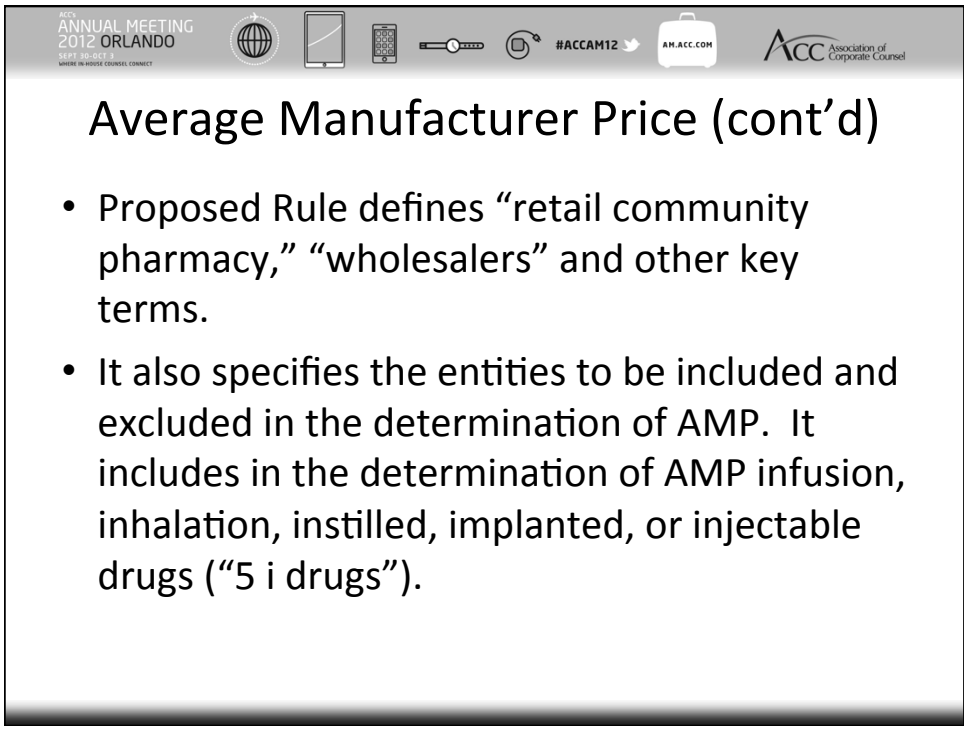
- CMS estimates approximately $17.7 billion in savings for federal fiscal years 2010 through 2014 ($3.7 billion federal savings and $4 billion in state savings)
- CMS estimates MCOs, drug manufacturers and States will incur costs of $81.4 million to implement the new requirements



Definition of Covered Outpatient Drug

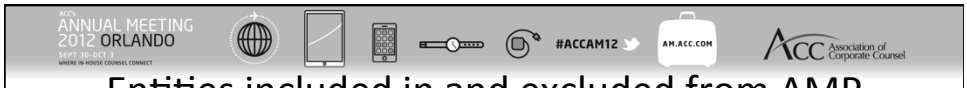
- Prescription drug that is medically necessary, approved as safe and effective by FDA (or which is identical, similar or related to such drugs)
- Requires each covered outpatient drug to have a national drug code (NDC) number and be listed electronically with the FDA
- Manufacturers will be required to report to CMS the number of an approved FDA application for a product or otherwise show the product meets the statutory definition of a covered outpatient drug





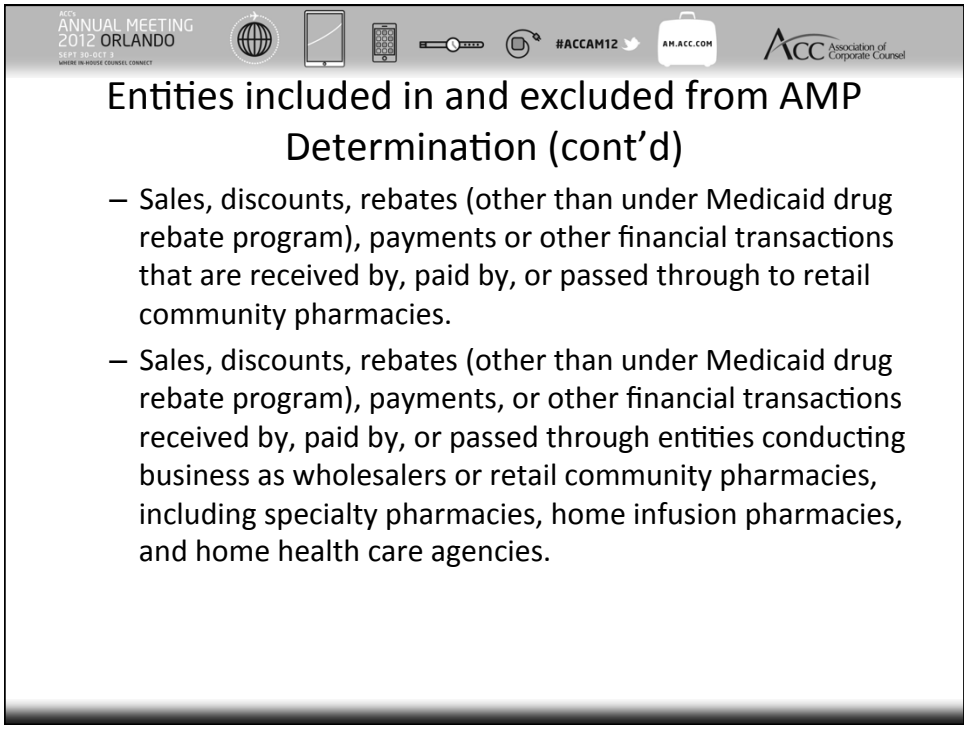
Manufacturer Calculation of AMP

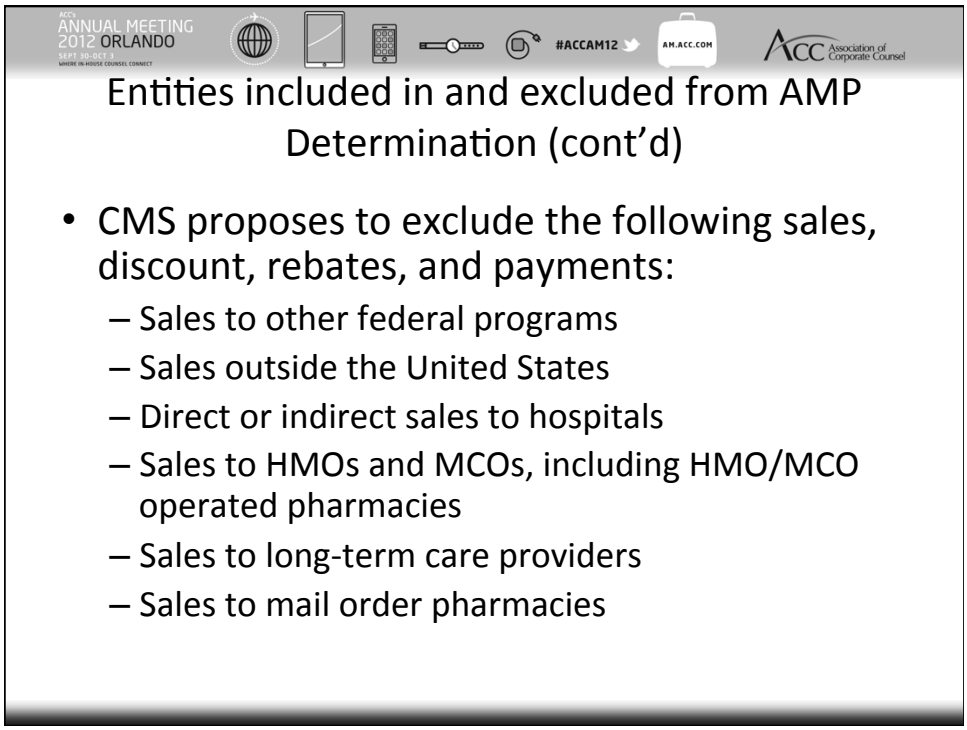
- Manufacturer holding the NDA of an authorized generic drug will be required to include in its calculation of AMP, its sales of authorized generic drugs directly to a wholesaler.
- Primary manufacturer will be required to include in its calculation of AMP its sale of authorized generic drugs that have been sold or licensed to a secondary manufacturer (including transfer prices and fees paid by the secondary manufacturer to the primary manufacturer when the secondary manufacturer acts as a wholesaler).

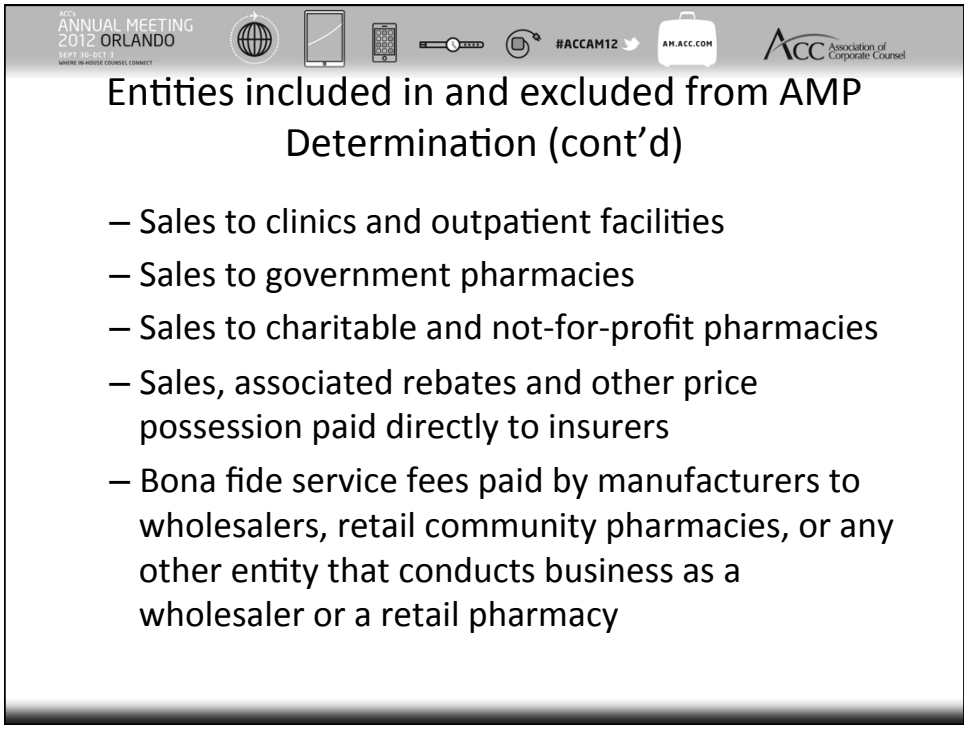


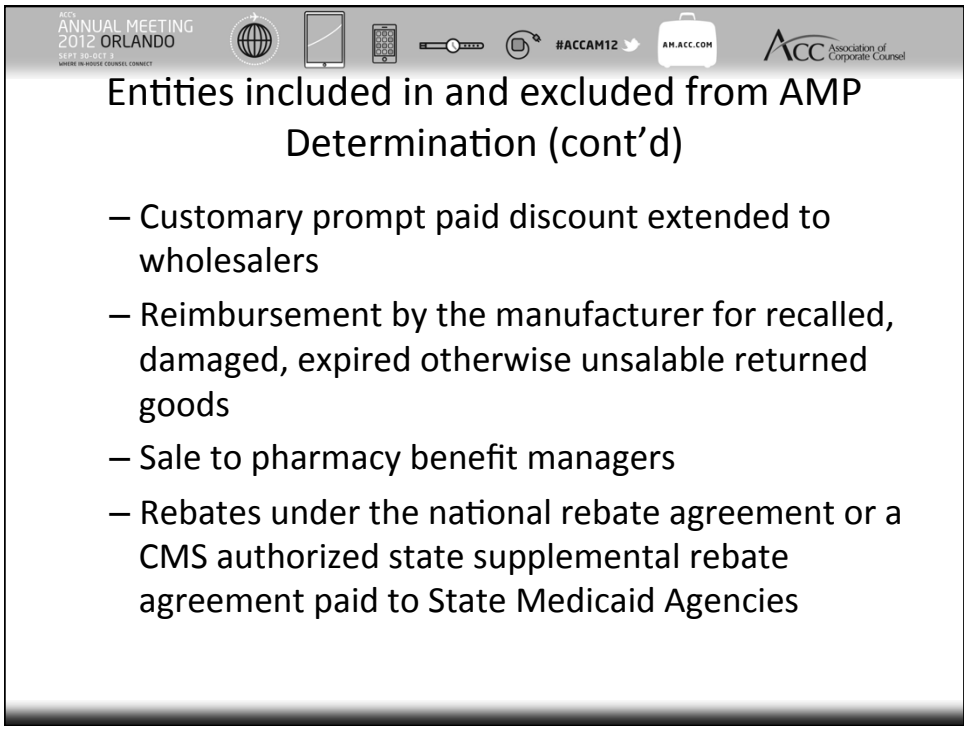
Entities included in and excluded from AMP Determination

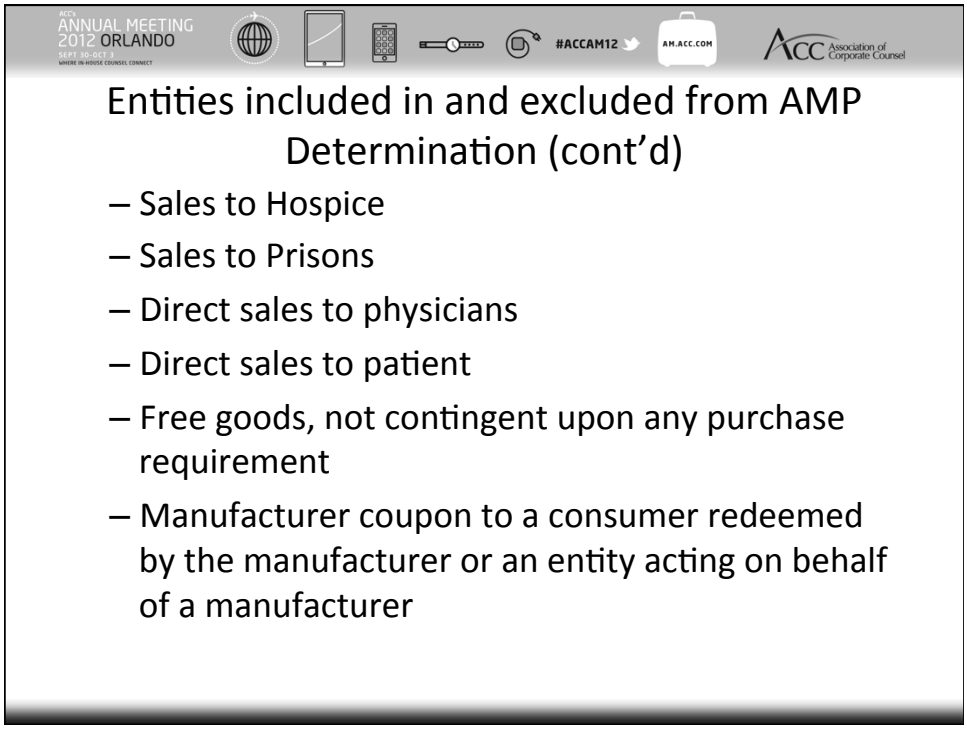
- CMS proposes to include the following sales, discounts, rebates, payments, nominal price sales and other transactions:
  - Sales to wholesalers for drugs dispensed to retail community pharmacies
  - Sales to other manufacturers who act as wholesalers for drugs distributed to retail community pharmacies

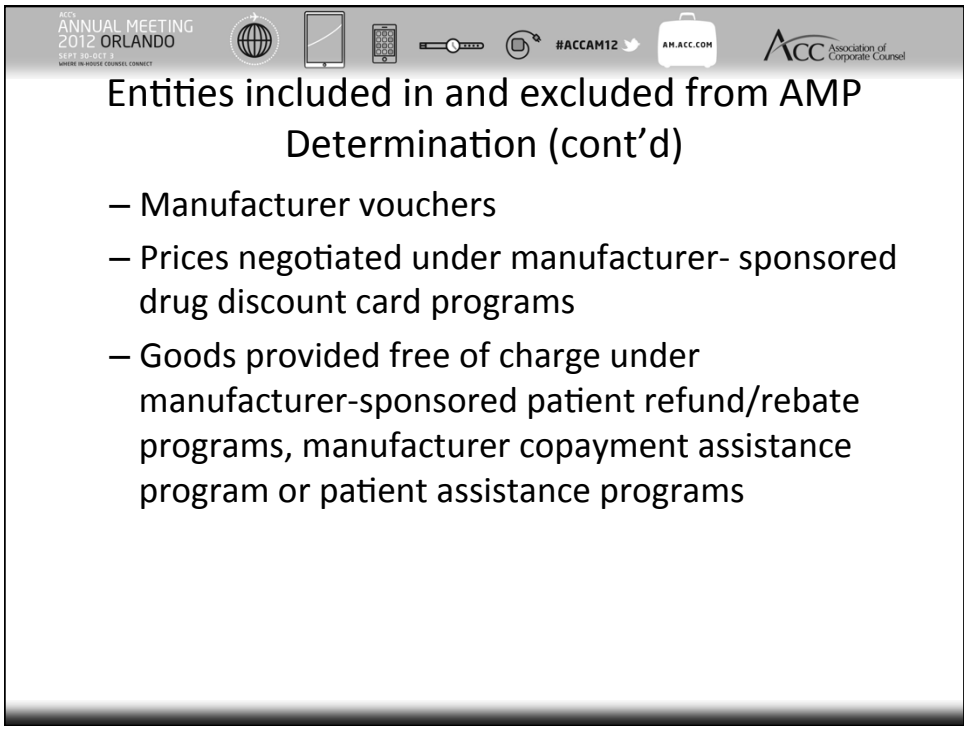


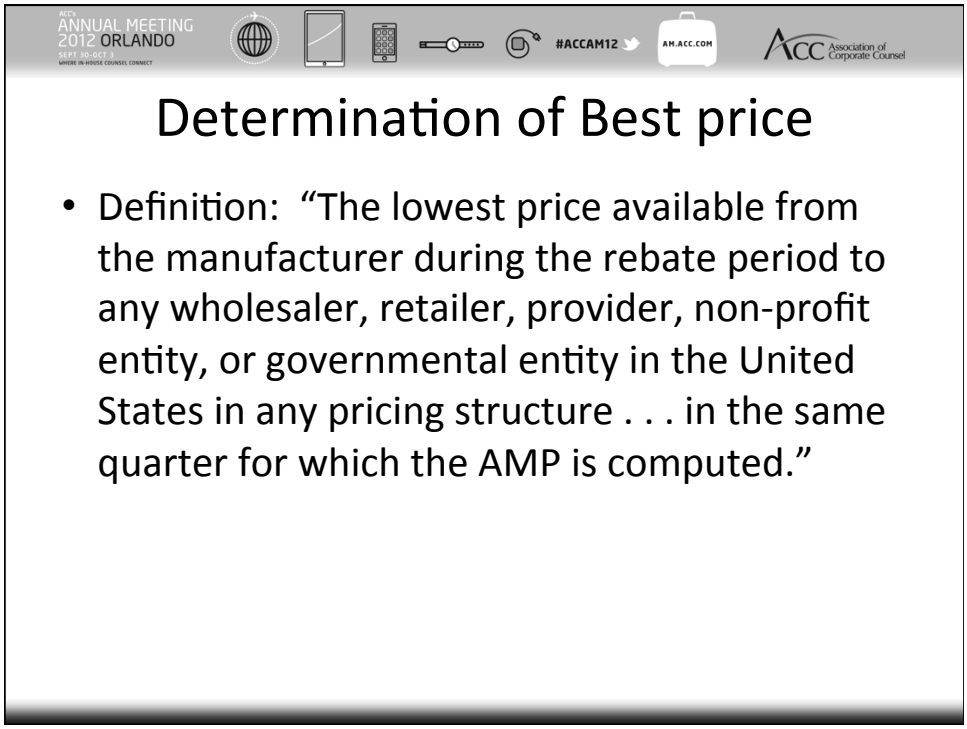


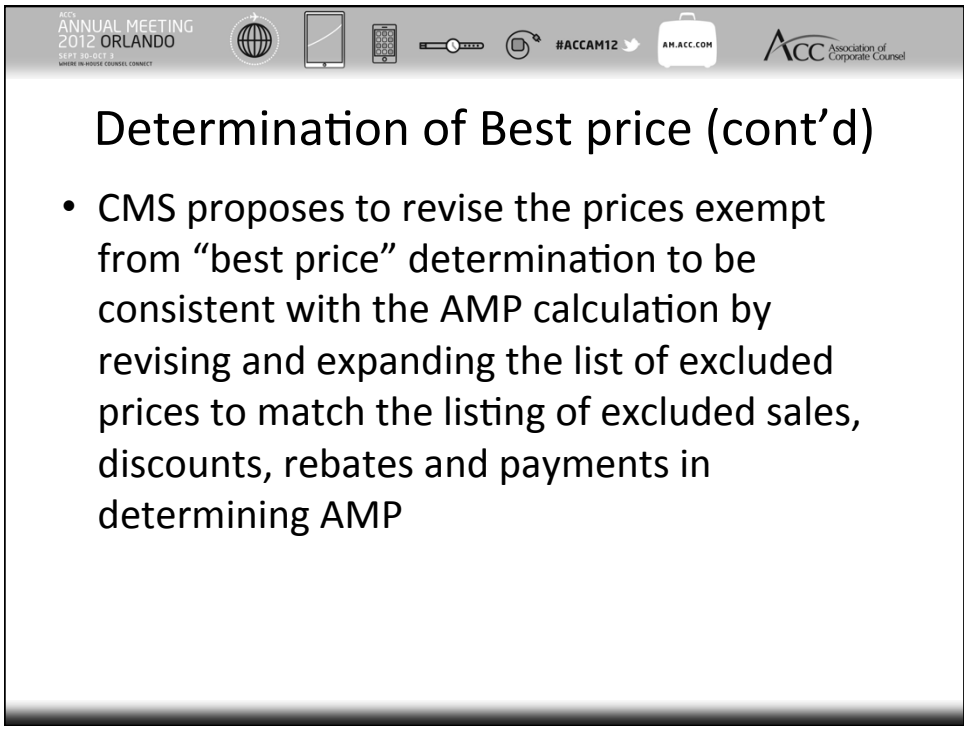


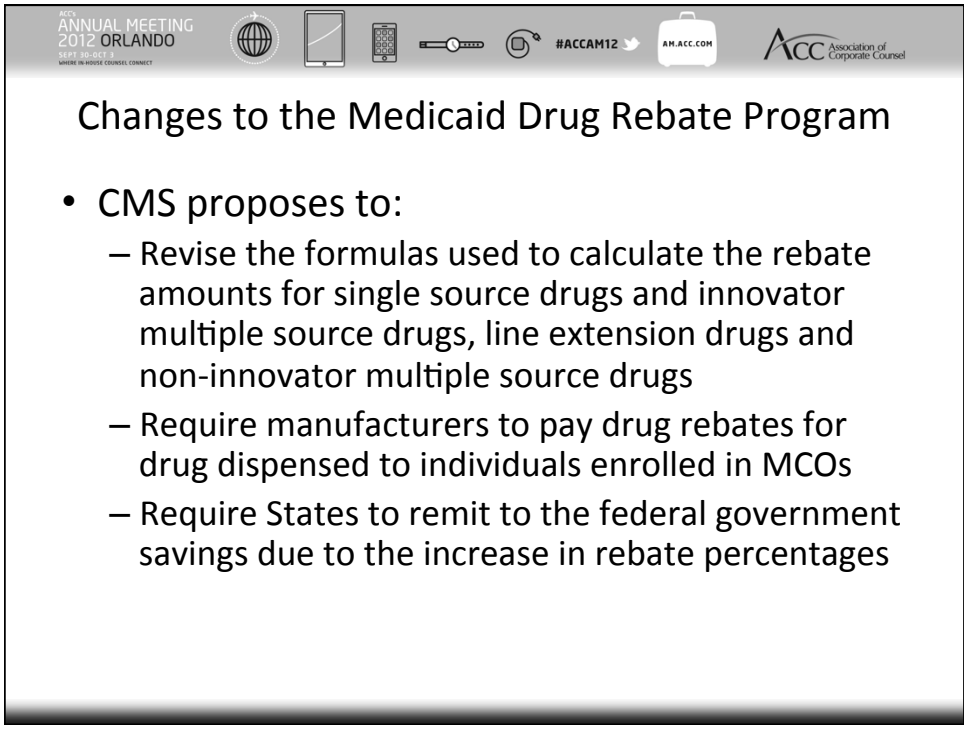


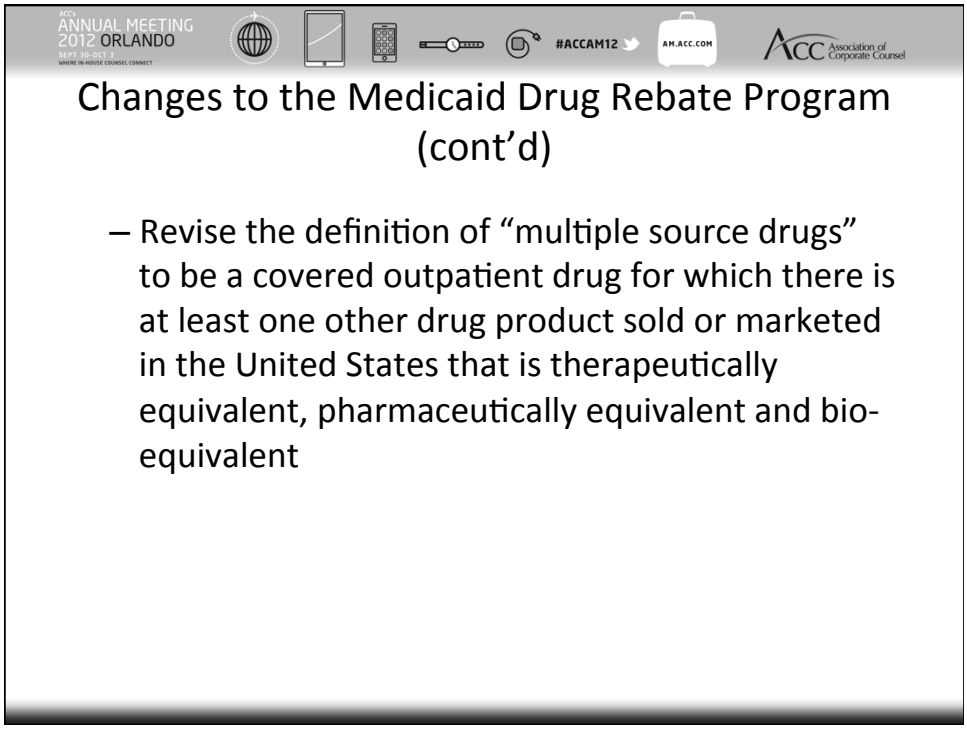


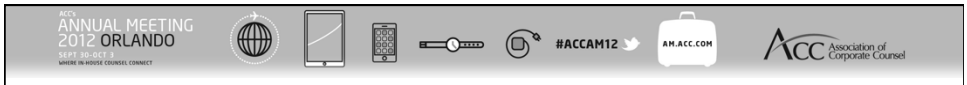










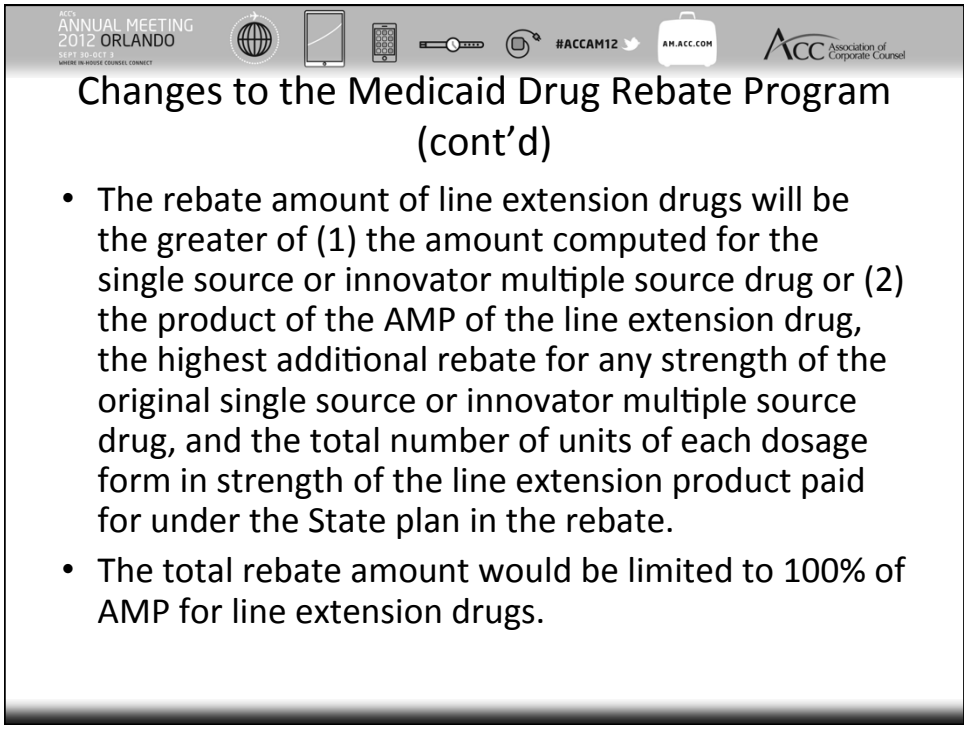


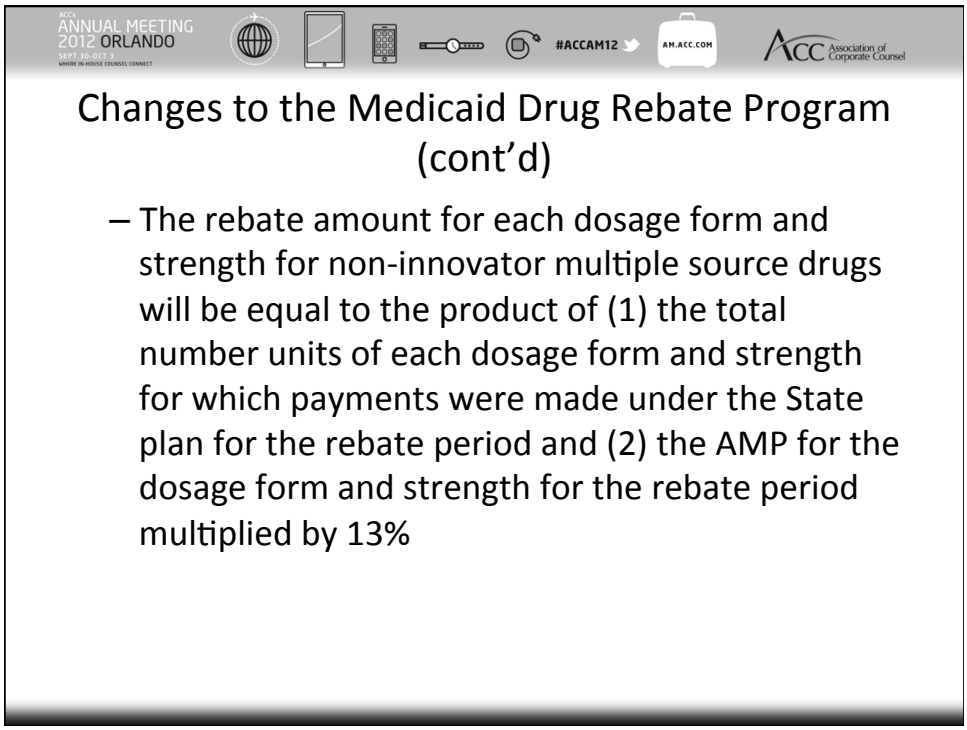
Changes to the Medicaid Drug Rebate Program (cont'd)

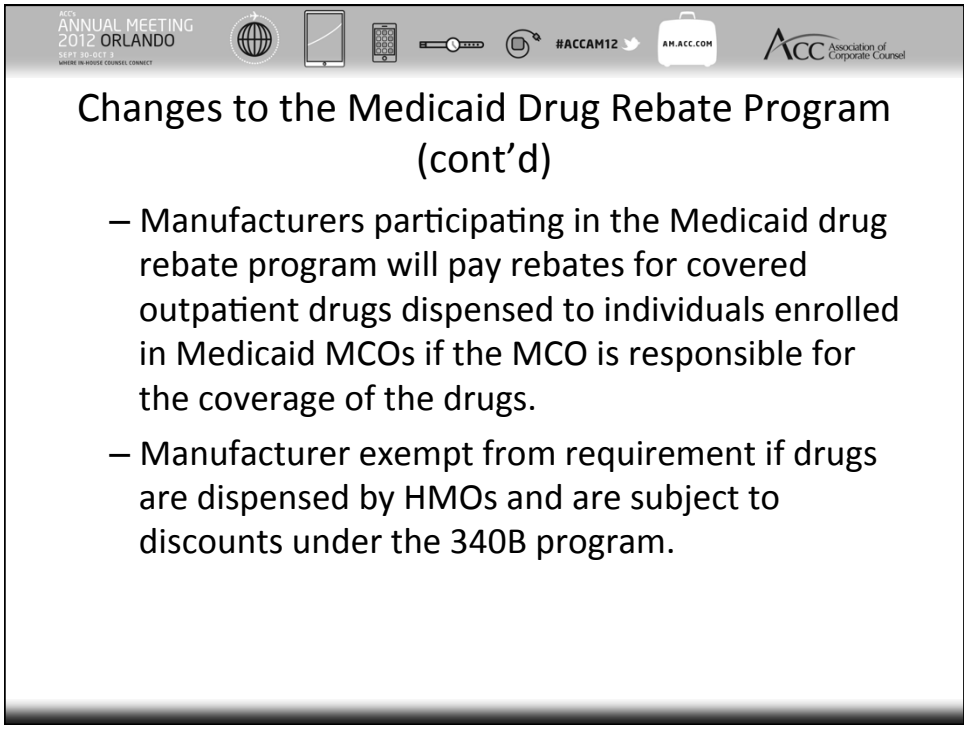
- Rebates for single source drugs and innovator multiple source drugs.
  - The amount of basic rebate for each dosage form and strength of a single source drug or an innovator multiple source drug will be equal to the product of the total number of units of each dosage form and strength paid for under the State plan in the rebate period and the greater of (1) the difference between the AMP and best price of the drug or (2) the AMP multiplied by 23.1%, or where applicable, 17.1%

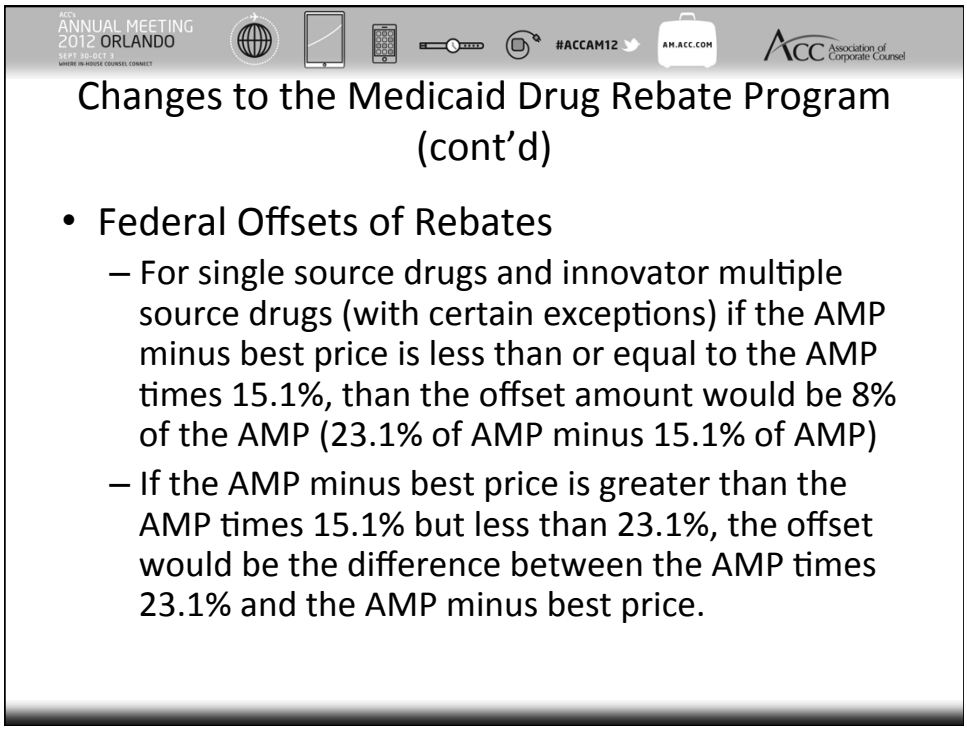
Changes to the Medicaid Drug Rebate Program (cont'd)

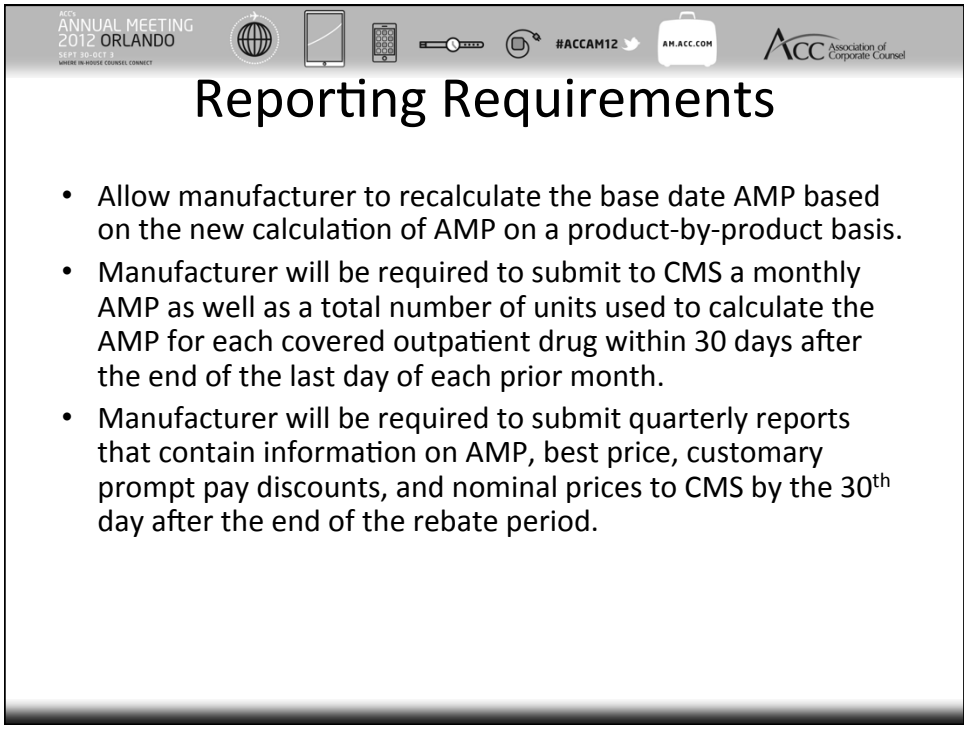
  - The rebate amount for each such drug would be increased by an additional rebate amount equal to the product of (1) the total number of units of such dosage form and strength paid for under the State plan in the rebate period and (2) the amount by which the AMP for the dosage form and strength of the drug for the period exceeds and adjusts based date AMP for such dosage form and strength.
  - The total rebate will be limited to 100% of the AMP of the drug.

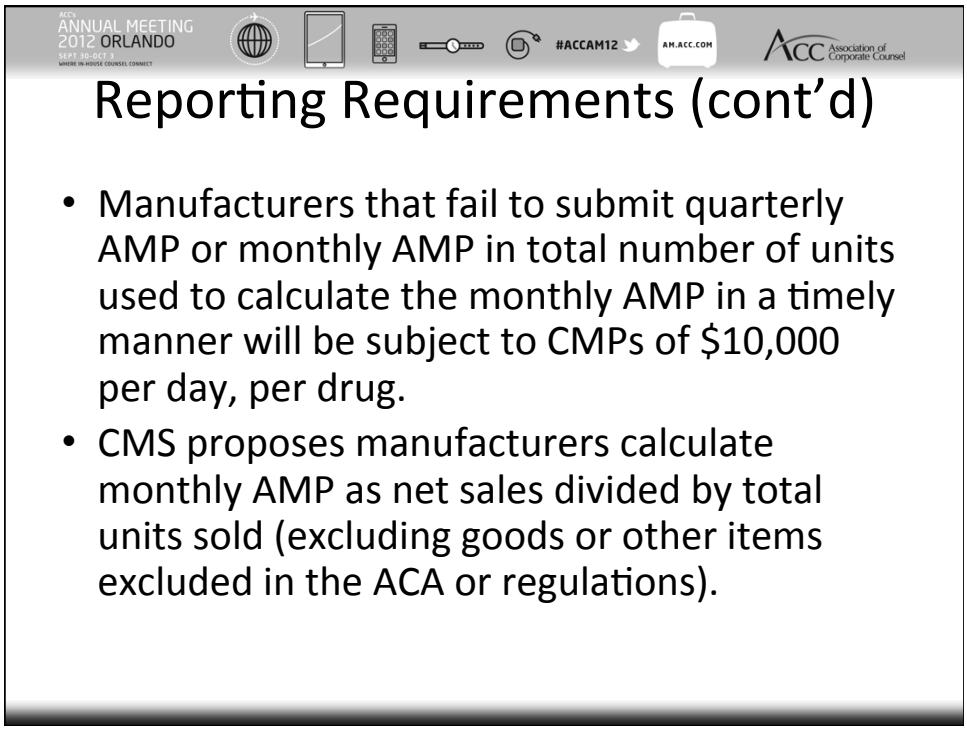


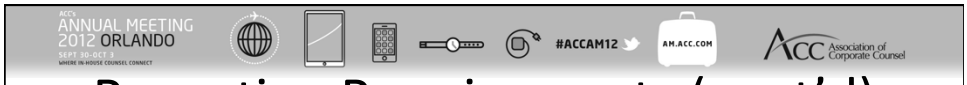






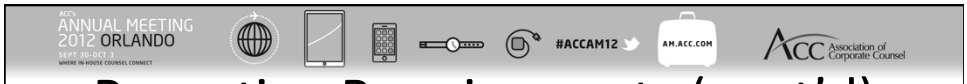






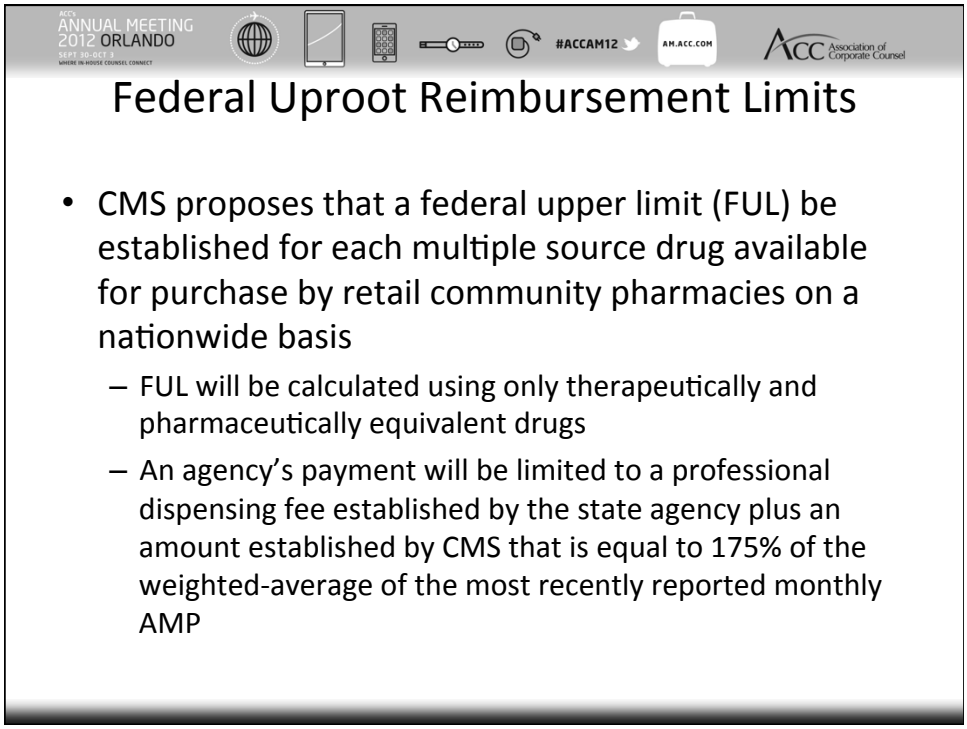
Reporting Requirements (cont'd)

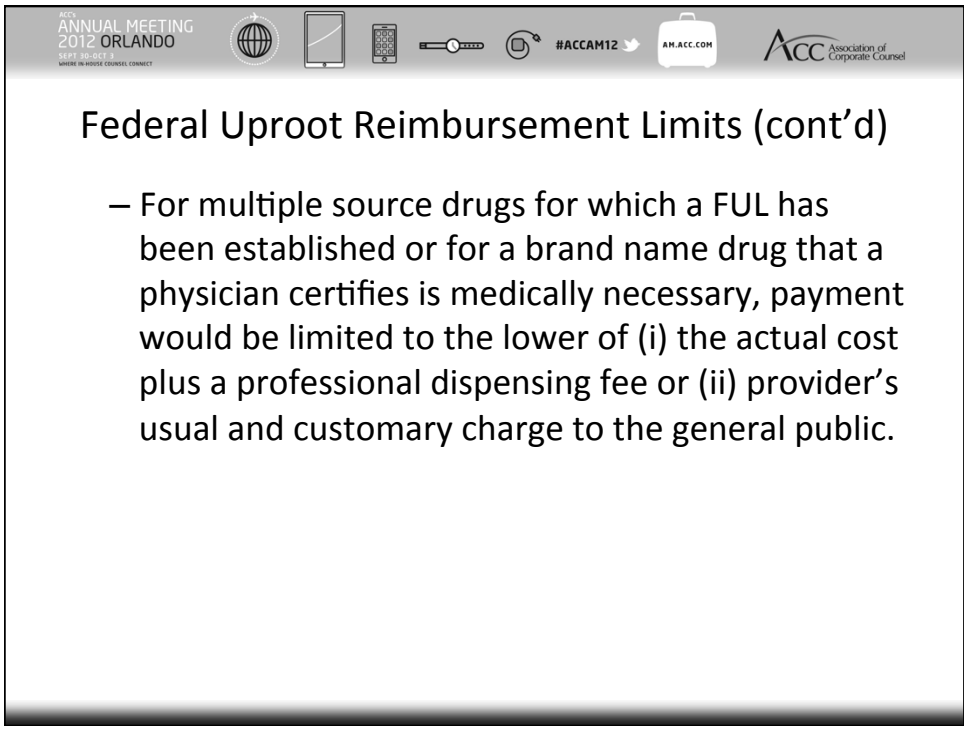
- The monthly AMP will be calculated based on the weighted average of prices for all the manufacturer's package sizes of each covered outpatient drug sold by the manufacturer during a month
- Manufacturer will be required to use a 12-month rolling percentage to estimate the value of lagged price concessions
- Manufacturers will be required to report to CMS revisions to monthly AMP within 36 months



Reporting Requirements (cont'd)

- Manufacturers will have 12 quarters to report changes to the AMP, best price, customary prompt pay discounts and nominal prices included in their quarterly reports.





Risk – Benefit Acknowledgement Form

Date: / /

Facility:

Resident: | Medication: | Dose:

This form is intended to facilitate the multidisciplinary evaluation and documentation of the use of any and/or all medications of concern identified in the Plan of Care (POC) to assure quality resident care as well as promoting the following medication management principles:

- The use of non-pharmacological interventions, when applicable, to minimize the need for medications, permit use of the lowest possible dose, or allow medications to be discontinued, and;
- Selection of medication(s) based on assessing relative benefits and risks to the individual resident while assuring the use of medications in doses and for the duration appropriate to each resident's clinical conditions, age, and underlying causes of symptoms, and;
- Evaluation of a resident's signs and symptoms, in order to identify the underlying cause(s), including adverse consequences of medications, and;
- The monitoring of medications for efficacy and clinically significant adverse consequences.

INSTRUCTIONS: Information from the resident's medical chart is to be utilized to complete the following sections. This information can be abstracted by facility staff and then acknowledged, by signature, by members of the care team as well as the resident/legally responsible party.

EVALUATION

1. The above resident was determined to have the following: _____
   (provide medical and/or psychiatric diagnosis – if dementia, complete #2)
2. The above diagnosis manifests as: _____
   (resident's target behavioral symptom(s) resulting from dementia with associated psychosis and/or agitated behaviors - not from environmental or psychosocial causes)

SELECTION

The above medication was initiated because (check all that apply):

☐ Non-pharmacological treatments/interventions utilized by staff (listed below) did not improve resident's clinical and/or functional status:
_____

☐ Resident posed an immediate harm to him-/herself or to other resident(s) as noted in the medical chart (specify date & section of chart):
_____

☐ Other documentation or conditions warranting selection, such as psychiatric consult (specify date & section of chart): _____
_____

MONITORING

1. Clinical and/or functional improvements continues to be monitored by (specify staff) _____
   and are documented in _____ section of medical chart.
2. Gradual dose reductions (if appropriate) continue to be monitored by (specify staff) _____
   and are documented in _____ section of medical chart.
3. Adverse medication reactions (if any) continue to be monitored by (specify staff) _____
   and are documented in _____ section of medical chart.
4. Other (specify) _____
   and are documented in _____ section of medical chart.

ACKNOWLEDGEMENT

The above information is believed to provide a current and representative summary of use of the specified medication for the above resident; as such it provides source(s) of documentation which support the continued use of the medication due to the clinical/functional benefits provided to the resident beyond any documented (or potential) risks related to the medication.

Signatures of Care Team and Resident/Legally Responsible Party (per facility policy):

Medical Director		Date: / /
Attending Physician		Date: / /
Director of Nursing		Date: / /
MDS RN Coordinator		Date: / /
Consultant Pharmacist		Date: / /
Other (specify):		Date: / /
Resident/Legally Responsible Party		Date: / /

WHITE - File or Care Plan YELLOW - Physician PINK - Director of Nursing

Consultant Pharmacist Medication Regimen Review (MRR) and Physician Notification

INSTRUCTIONS: After reviewing the MDS and/or information from the resident's medical chart, indicate the appropriate item/area of concern and make "Comment" to the right of this form. Original copy of irregularities needing Physician input to be sent to Physician for evaluation, action and signature. Pharmacist copy to be retained by Pharmacist. Upon receipt of Physician's signed original, adhere to facility/chart copy.

1. POTENTIAL MEDICATION IRREGULARITIES

A. Medication Classes of Known Risk (See Table 1, adapted from CMS guidelines)

1. Analgesics	15. Cough, Cold, and Allergy
2. Antiobiotics	16. Gastrointestinal
3. Anticoagulants	17. Glucocorticoids
4. Anticonvulsants	18. Hematinics
5. Antidepressants	19. Laxatives
6. Antidiabetic	20. Muscle Relaxants
7. Antifungals	21. Orexigenics (Appetite Stimulants)
8. Antimanic	22. Osteoporosis
9. Antiparkinson	23. Platelet Inhibitors
10. Antipsychotic	24. Respiratory
11. Anxiolytics	25. Sedatives/Hypnotics (Sleep Medications)
12. Cardiovascular (Including Antihypertensives)	26. Thyroid
13. Cholesterol Lowering	27. Urinary Incontinence
14. Cognitive Enhancers	

B. Medication Classes + Diagnosis of Known Risk (See Table 2)

Current CMS Guidance (Table 1) addresses many drug-diagnosis problems to be reviewed by the consultant pharmacist; this form incorporates reproduction of the most recent Beers data

Disease or Condition:

- Heart Failure
- Hypertension
- Gastric or Duodenal Ulcers
- Seizures or Epilepsy
- Blood Clotting Disorders or Receiving Anticoagulant Therapy
- Bladder Outflow Obstruction
- Stress Incontinence
- Arrhythmias
- Insomnia
- Parkinson Disease
- Cognitive Impairment
- Depression
- Anorexia and Malnutrition
- Syncope or Falls
- SIADH/Hyponatremia
- Seizure Disorder
- Obesity
- COPD
- Chronic Constipation

C. Medication Interaction [illegible]sks

Adapted from CMS Guidance (S[illegible] Table 3) f[illegible]oy the cons[illegible] pharmacist; see Gu[illegible]e for full [illegible]ail

D. Medicatio[illegible]n [illegible]A War[illegible]gs

Food and D[illegible] Administ[illegible]on (FL[illegible] requirement[illegible] manufacturers include within th[illegible]edication l[illegible]g warn[illegible]s about a[illegible]se reactions and potential safet[illegible]zards ide[illegible] befo[illegible]nd after a[illegible]oval of a medication, and wh[illegible] do if the[illegible] [illegible] this and [illegible]k box warnings visit: w[illegible].fda.gov/[illegible]/safety.h[illegible] comp[illegible]th the investigative Protocol F329 the c[illegible]ant pharmacis[illegible] fail to monitor a medication nsistent wi[illegible]e current standar[illegible]tice or manufacturer's guidelines.

[illegible] Other Medica[illegible] Related [illegible]oblems

P[illegible]em:	Date:
Probl[illegible]	Date:
Problem:	Date:

2. [illegible]UATION(S) NEEDING POSSIBLE MEDICATION INTERVENTION

As part of the investigative protocol for compliance with the MRR, the consultant pharmacist should identify clinical conditions experienced by the resident which would benefit from pharmacological intervention

3. SITUATION(S) NEEDING POSSIBLE NON-PHARMACOLOGICAL INTERVENTION

Intent (excerpted) of 483.25(l)
Non-pharmacological interventions (such as behavioral interventions) are considered and used when indicated, instead of, or in addition to, medication

PHYSICIAN'S COPY
Must be signed and returned according to facility policy.

Consultant Pharmacist Medication Regimen Review (MRR) and Physician Notification

Federal Tag F428 Interpretive Guidelines, 483.60(c): requires medication regimen reviews by a licensed pharmacist at least monthly with an apparent irregularities report to the MD and DON for review and action.

Dear Physician,

The above regulation requires notifying you of potential medication therapy problems. For further explanation of potential problem see the reverse side of this form. To facilitate this process we are providing this form: please evaluate, respond, sign and return to this facility.

Facility Staff/ Consulting R.Ph.

☐ Above Irregularities Noted By: Physician Date

Since last MRR: Triggered CAA(s): (see table 4) 1 2 3 4 5 6 7 8 9 10 / 11 12 13 14 15 16 17 18 19 20

Physician's Name:

Resident Name | Facility Name | Date

Comment code(s): *(circle and explain below)* 1A 1B 1C 1D 1E 2 3 *(see criteria on reverse)*

To: ☐ Physician ☐ Nursing

No. Of Meds. _____ ☐ No Irregularities Noted

Physician/Facility Response:

All resulting order(s) to be transcribed to accepted order form per facility policy.

R.Ph. Date Nurse Date

☐ Therapy adjusted
☐ No adjustment due to documented benefit (outweighing risk)
☐ OTHER, explain:

PHYSICIAN'S COPY - Please Sign and Return

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- Depression
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- Seizure Disorder
- Obesity
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C. Medication Interaction Risks

Adapted from CMS Guidance (See Table 3) for review by the consultant pharmacist; see Guidance for full detail

D. Medication with FDA Warnings

Food and Drug Administration (FDA) requirement that manufacturers include within the medication labeling warnings about adverse reactions and potential safety hazards identified both before and after approval of a medication, and what to do if they occur. (For more on this and black box warnings visit: www.fda.gov/medwatch/safety.htm To comply with the investigative Protocol or F329 the consultant pharmacist should not fail to monitor a medication consistent with the current standard of practice or manufacturer's guidelines.

E. Other Medication Related Problems

Problem: Date:

2. SITUATION(S) NEEDING POSSIBLE MEDICATION INTERVENTION

As part of the investigative protocol for compliance with the MMR, the consultant pharmacist should identify clinical conditions experienced by the resident which would benefit from pharmacological intervention

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PHARMACIST'S COPY

Consultant Pharmacist Medication Regimen Review (MRR) and Physician Notification

Federal Tag F428 Interpretive Guidelines, 483.60(c): requires medication regimen reviews by a licensed pharmacist at least monthly with an apparent irregularities report to the MD and DON for review and action.

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Facility Staff/ Consulting R.Ph.

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Physician's Name:

Resident Name | Facility Name | Date

Comment code(s): *(circle and explain below)* 1A 1B 1C 1D 1E 2 3 *(see criteria on reverse)*

To: ☐ Physician ☐ Nursing

No. Of Meds. _____ ☐ No Irregularities Noted

Physician/Facility Response:

All resulting order(s) to be transcribed to accepted order form per facility policy.

R.Ph. Date Nurse Date

☐ Therapy adjusted ☐ OTHER, explain:

☐ No adjustment due to documented benefit (outweighing risk)

PHARMACIST'S COPY

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FACILITY CHART COPY

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OTHER, explain:

FACILITY CHART COPY - Adhere Signed Original

TABLE 1 MEDICATION CLASSES OF KNOWN RISK - Affecting the Long Term Care Resident

1. ANALGESICS

Acetaminophen

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

Non-selective NSAIDs, e.g.,

- aspirin
- diclofenac
- diflunisal
- ibuprofen
- indomethacin
- ketorolac
- meclofenamate
- naproxen
- piroxicam
- salicylates
- tolmetin

Cyclooxygenase-II (COX-2) inhibitors, e.g.,

- celecoxib

Opioid Analgesics

Short-acting, e.g.,

- codeine
- fentanyl
- hydrocodone
- hydromorphone
- meperidine
- morphine
- oxycodone

Long-acting, e.g.,

- fentanyl, transdermal
- methadone
- morphine, sustained release
- oxycodone, sustained release

Pentazocine

Propoxyphene and combination products with aspirin or acetaminophen

2. ANTIBIOTICS

All antibiotics

Parenteral vancomycin and aminoglycosides, e.g.,

- amikacin
- gentamycin/gentamicin
- tobramycin

Nitrofurantoin

Fluoroquinolones, e.g.,

- ciprofloxacin
- levofloxacin
- moxifloxacin
- ofloxacin

3. ANTICOAGULANTS

warfarin

4. ANTICONVULSANTS

All anticonvulsants, e.g.,

- carbamazepine
- gabapentin
- lamotrigine
- levetiracetam
- oxcarbazepine
- phenobarbital
- phenytoin
- primidone
- valproic acid

5. ANTIDEPRESSANTS

All antidepressants classes, e.g.,

Alpha-adrenoceptor antagonist, e.g.,

- Mirtazapine

Dopamine-reuptake blocking compounds, e.g.,

- Bupropion

Monoamine oxidase inhibitors (MAOIs)

Serotonin (5-HT 2) antagonists, e.g.,

- nefazodone
- trazodone

Selective serotonin-norepinephrine reuptake inhibitors (SNRIs), e.g.,

- duloxetine
- venlafaxine

Selective serotonin reuptake inhibitors (SSRIs), e.g.,

- citalopram
- escitalopram
- fluoxetine
- fluvoxamine
- paroxetine
- sertraline

Tricyclic (TCA) and related compounds

Monoamine oxidase inhibitors, e.g.,

- isocarboxazid
- phenelzine
- tranylcypromine

Tricyclic antidepressants (TCAs), e.g.,

- amitriptyline
- amoxapine
- doxepin

Combination products, e.g.,

- amitriptyline/chlordiazepoxide
- amitripytline/perphenazine

6. ANTIDIABETIC MEDICATIONS

Insulin and oral hypoglycemics, e.g.,

- acarbose
- acetohexamide
- chlorpropamide
- glimepiride
- glipizide
- glyburide
- repaglinitazone
- tolazamide
- tolbutamide

Including combination products, e.g.,

- rosiglitazone/metformin
- glyburide/metformin
- glipizide/metformin
- pioglitazone/metformin

chlorpropamide

glyburide

7. ANTIFUNGALS

Imidazoles for systemic use, e.g.,

- fluconazole
- itraconazole
- ketoconazole

8. ANTIMANIC MEDICATIONS

Lithium

9. ANTIPARKINSON MEDICATIONS

All classes, e.g.,

Catechol-O-Methyl Transferase (COMT) Inhibitors, e.g.,

- Entacapone

Dopamine agonists, e.g.,

- bromocriptine
- ropinirole
- pramipexole

MAO inhibitors, e.g.,

- selegiline

Others, e.g.,

- amantadine

Various dopaminergic combinations, e.g.,

- carbidopa/levodopa
- carbidopa/levodopa/entacapone

10. ANTIPSYCHOTIC MEDICATIONS

All classes, e.g.,

First generation (conventional) agents, e.g.,

- chlorpromazine
- fluphenazine
- haloperidol
- loxapine
- mesoridazine
- molindone
- perphenazine
- promazine
- thioridazine
- thiothixene
- trifluoperazine
- triflupromazine

Second generation (atypical) agents, e.g.,

- aripiprazole
- clozapine
- olanzapine
- quetiapine
- risperidone
- ziprasidone

Daily Dose Thresholds for Anitpsychotic Medications Used to Manage Behavioral Symptoms Related to Dementing Illnesses

GENERIC MEDICATION	DOSAGE
First Generation	
chlorpromazine	75 mg
fluphenazine	4 mg
haloperidol	3 mg
loxapine	30 mg
molindone	10 mg
perphenazine	8 mg
pimozide	*
prochloroperazine	*
thioridazine	75 mg
thiothixene	7 mg
trifluoperazine	8 mg
Second Generation	
aripiprazole	10 mg
olanzapine	5 mg
quetiapine	50 mg
risperidone	1 mg
ziprasidone	*

* Not recommended for the treatment of behavioral symptoms

11. ANXIOLYTICS

All Anxiolytics

Benzodiazepines

Short-acting, e.g.,

- alprazolam
- estazolam
- lorazepam
- oxazepam
- temazepam

Long-acting, e.g.,

- chlordiazepoxide
- clonazepam
- clorazepate
- diazepam
- flurazepam
- quazepam

Buspirone

Total Daily Dose Thresholds for Anxiolytic Medications

GENERIC MEDICATION	DOSAGE
flurazepam	15 mg
chlordiazepoxide	20 mg
clorazepate	15 mg
diazepam	5 mg
clonazepam	1.5 mg
quazepam	7.5 mg
estazolam	0.5 mg
alprazolam	0.75 mg
oxazepam	30 mg
lorazepam	2 mg

Other antidepressants except bupropion

diphenhydramine and hydroxyzine

meprobamate

12. CARDIOVASCULAR MEDICATIONS (Including Antihypertensives)

All antiarrhythmics

amiodarone

disopyramide

All antihypertensives

Alpha blockers, e.g.,

- alfuzosin
- doxazosin
- prazosin
- tamsulosin
- terazosin

Angiotensin converting enzyme (ACE) inhibitors, e.g.,

- benazepril
- captopril
- enalapril
- fosinopril
- lisinopril

Angiotensin II receptor blockers, e.g.,

- candesartan
- eprosartan
- irbesartan
- losartan
- olmesartan
- valsartan

Beta adrenergic blockers, e.g.,

Nonselective, e.g.,

- propranolol

Cardioselective, e.g.,

- atenolol
- esmolol
- metoprolol
- nadolol
- timolol

Calcium channel blockers, e.g.,

- nifedipine
- isradipine
- amlodipine
- isoldipine
- diltiazem
- verapamil

methyldopa

Including combination products such as methyldopa hydrochlorothiazide

Digoxin

Diuretics, e.g.,

- bumetanide
- ethacrynic acid
- furosemide
- hydrochlorothiazide
- metolazone
- spironolactone
- torsemide
- triamterene

Nitrates, e.g.,

- isosorbide dinitrate
- isosorbide mononitrate
- nitroglycerin

13. CHOLESTEROL LOWERING MEDICATIONS

HMG-CoA Reductase Inhibitors ("statins"), e.g.,

- atorvastatin
- fluvastatin
- lovastatin
- pravastatin
- rosuvastatin
- simvastatin

cholestyramine

fibrates, e.g.,

- fenofibrate
- clofibrate

niacin

14. COGNITIVE ENHANCERS

Cholinesterase inhibitors, e.g.,

- donepezil
- galantamine
- rivastigmine

NMDA receptor antagonists, e.g.,

- memantine

15. COUGH, COLD, AND ALLERGY MEDICATIONS

All cough, cold, allergy medications

Antihistamine H-1 blockers, e.g.,

- chlorpheniramine
- cyproheptadine
- diphenhydramine
- hydroxyzine
- meclizine
- promethazine

Oral decongestants, e.g.,

- pseudoephedrine

16. GASTROINTESTINAL MEDICATIONS

Phenothiazine-related antiemetics, e.g.,

- prochlorperazine
- promethazine

trimethobenzamide

metoclopramide

Proton pump inhibitors (PPI), e.g.,

- esomeprazole
- lansoprazole
- omeprazole
- rabeprazole

H-2 antagonists, e.g.,

- cimetidine
- famotidine
- ranitidine

17. GLUCOCORTICOIDS

All glucocorticoids (except topical or inhaled dosage forms), e.g.,

- dexamethasone
- hydrocortisone
- methylprednisolone
- prednisone

18. HEMATINICS

Erythropoiesis stimulants, e.g.,

- darbepoetin
- erythropoietin

Iron

19. LAXATIVES

All categories including bulk producing laxatives, hyperosmolar agents, saline laxatives, stimulant laxatives, emollient laxatives

TABLE 1 MEDICATION CLASSES OF KNOWN RISK - Affecting the Long Term Care Resident *(Continued)*

20. MUSCLE RELAXANTS

All muscle relaxants, e.g.,
- baclofen
- carisoprodol
- chlorzoxazone
- cyclobenzaprine
- dantrolene
- metaxalone
- methocarbamol
- orphenadrine

21. OREXIGENICS (Appetite Stimulants)

All appetite stimulants, e.g.,
- megesterol acetate
- oxandrolone
- dronabinol

22. OSTEOPOROSIS MEDICATIONS

Bisphosphonates, e.g.,
- alendronate
- ibandronate
- risedronate

23. PLATELET INHIBITORS

All platelet inhibitors, e.g.,
- dipyridamole
- aspirin
- clopidogrel
- dipyridamole extended-release and aspirin (as fixed-dose combination)

ticlopidine

24. RESPIRATORY MEDICATIONS

theophylline

Inhalant medications classes, e.g.,

Anticholinergic, e.g.,
- ipratropium
- tiotropium

Beta 2 agonists, e.g.,
- albuterol
- formoterol
- pirbuterol acetate
- salmeterol

Corticosteroids, e.g.,
- beclomethasone
- budesonide
- flunisolide
- fluticasone
- triamcinolone acetonide

Miscellaneous, e.g.,
- cromolyn
- nedocromil sodium

25. SEDATIVES/HYPNOTICS (Sleep Medications)

All hypnotics

Benzodiazepine hypnotics, e.g.,
- estazolam
- flurazepam
- quazepam
- temazepam
- triazolam

Non-benzodiazepine hypnotics, e.g.,
- eszopiclone
- zaleplon
- zolpidem

Melatonin receptor agonists, e.g.,
- ramelteon

Other hypnotics, e.g.,
- chloral hydrate

Miscellaneous agents used for sleep, e.g.,
- sedating antidepressants (e.g., trazodone)
- sedating antihistamines (e.g., hydroxyzine)

Daily Dose Thresholds For Sedative-Hypnotic Medications

GENERIC MEDICATION	ORAL DOSAGE
chloral hydrate*	500 mg
diphenhydramine*	25 mg
estazolam	0.5 mg
eszopiclone	1 mg
flurazepam*	15 mg
hydroxyzine*	50 m
lorazepam	1
oxazepam	mg
quazepam*	5 mg
ramelteon	8 mg
temazepam	mg
triazolam*	0.1 mg
zaleplon	
zolpidem IR	5
zolpidem CR	6.

*These medications not ...idered medications o... the management of in...nia, especially in older in...lu...

Barbiturates, e.g.,
- amobarbital
- butabarbi...
- pento...bi...
- se...al
- phe...arbital
- amo...bital ...obarbit...
- barbi... ...ith oth...edications

26. THYROID MEDICATIONS

All thyroid medications, e.g.,
- levothyroxine
- triiodothryonine

27. URINARY INCONTINENCE MEDICATIONS

Urinary Incontinence Types and Agents, e.g.,

Urge incontinence: Anticholinergics, e.g.,
- darifenacin
- oxybutynin
- tolterodine
- trospium

Tricyclic antidepres... ...g.,
- desipramine
- imipramine

Stress incontine... Alpha a... ...ergic agonists, e.g.,
- pseudoeph... ...ine

Mixed inco... ...ence, e...
- estro... replacer... ...ad...
- ...ramine

Over... incontin... ...e, ...
- ...na adrenerg... ...onist... ...ee ...ertensives)
- ...anechol chlo... ...e

SOU...
C... ...s for Medicaid and Medicare Services, ...nsmittal 22, December 15, 2006. Available at http://www.cms.hhs.gov/transmittals/downloads/R22SOMA.pdf

TABLE 2 2002 CRITERIA FOR POTENTIALLY ...APPROPR...TE ...EDICATI... USE IN OLDER ADULTS: Considering Diagnoses or Conditions

Disease or Condition	Drug	Concern	Severity Rating (High or Low)
Heart failure	Disopyramide (No...ne), a...tig...odium ...tent drugs (s...um ...sodium salts [alginate bicarb...te, biphos...nitrate ...sphate, salic...te, ...d sulfate])	Negative inotropic effect. Potential to promote fluid retention and exacerbation of heart failure.	High
Hypertension	Phenylpro...amine hydrochlo...remo...m the ma...n 2001), pseudoe...rine; diet pills, and a...etami...	May produce elevation of blood pressure secondary to sympathomimetic activity.	High
Gastric or duodenal ulcers	NSAIDs a...spirin (>325 ...g) (coxibs exclu...)	May exacerbate existing ulcers or produce new/additional ulcers.	High
Seizures or epilepsy	...apine (C...ril), chlorpro... (Thorazin... thioridazine (Mellaril), ...thothixen... (Navane)	May lower seizure thresholds.	High
Blood clotting disorders or receiving anticoagulant thera...	Aspir... ...SAIDs, ...yridamole (...a... ...clopidine (Ticlid), ...clopidogrel (Plavix)	May prolong clotting time and elevate INR values or inhibit platelet aggregation, resulting in an increased potential for bleeding.	High
Bladder outflow ...truction	Anticholinergic... ...d a...istami..., gastrointestinal antispasmodics, ...muscle relaxants, ...h...in ...opan), flavoxate (Urispas), anticholinergics, ...idepressants, de... ..., and tolterodine (Detrol)	May decrease urinary flow, leading to urinary retention.	High
Stress incontin...e	...-...kers (Doxazosin ...zosin, and Terazosin), anticholinergics, ...c antidepressa... imipramine hydrochloride, doxepin hydrochloride, ...amitriptyline h...chloride) and long-acting benzodiazepines	May produce polyuria and worsening of incontinence.	High
...rhythmias	Tricyclic ...sants (imipramine hydrochloride, doxepin hydrochloride, and a...ptyl... hydrochloride)	Concern due to proarrhythmic effects and ability to produce QT interval changes.	High
Insomn...	D... ...gestants, theophylline (Theodur), methylphenidate (Ritalin), MAOIs, ar... ...mphetamines	Concern due to CNS stimulant effects.	High
...-...	M... ...lopramide (Reglan), conventional antipsychotics, and tacrine (Cognex)	Concern due to their antidopaminergic/cholinergic effects.	High
...ve impairm...	...biturates, anticholinergics, antispasmodics, and muscle relaxants. CNS stimulants: dextroAmphetamine (Adderall), methylphenidate (Ritalin), methamphetamine (Desoxyn), and pemolin	Concern due to CNS-altering effects.	High
Depression	Long-term benzodiazepine use. Sympatholytic agents: methyldopa (Aldomet), reserpine, and guanethidine (Ismelin)	May produce or exacerbate depression.	High
...and ...trition	CNS stimulants: DextroAmphetamine (Adderall), methylphenidate (Ritalin), methamphetamine (Desoxyn), pemolin, and fluoxetine (Prozac)	Concern due to appetite-suppressing effects.	High
...ncope o... ...s	Short- to intermediate-acting benzodiazepine and tricyclic antidepressants (imipramine hydrochloride, doxepin hydrochloride, and amitriptyline hydrochloride)	May produce ataxia, impaired psychomotor function, syncope, and additional falls.	High
SIAD... ...yponatremia	SSRIs: fluoxetine (Prozac), citalopram (Celexa), fluvoxamine (Luvox), paroxetine (Paxil), and sertraline (Zoloft)	May exacerbate or cause SIADH.	Low
...eizure disorder	Bupropion (Wellbutrin)	May lower seizure threshold.	High
Obesity	Olanzapine (Zyprexa)	May stimulate appetite and increase weight gain.	Low
COPD	Long-acting benzodiazepines: chlordiazepoxide (Librium), chlordiazepoxide-amitriptyline (Limbitrol), clidinium-chlordiazepoxide (Librax), diazepam (Valium), quazepam (Doral), halazepam (Paxipam), and chlorazepate (Tranxene). β-blockers: propranolol	CNS adverse effects. May induce respiratory depression. May exacerbate or cause respiratory depression.	High
Chronic constipation	Calcium channel blockers, anticholinergics, and tricyclic antidepressant (imipramine hydrochloride, doxepin hydrochloride, and amitriptyline hydrochloride)	May exacerbate constipation.	Low

ABBREVIATIONS: **CNS** – central nervous systems; **COPD** – chronic obstructive pulmonary disease; **INR** – international normalized ratio; **MAOIs** – monoamine oxidase inhibitors; **NSAIDs** – nonsteroidal anti-inflammatory drugs; **SIADH** – syndrome of inappropriate antidiuretic hormone secretion; **SSRIs** – selective serotonin reuptake inhibitors.

Beers, M.H.: Updating the Beers Criteria from Potentially Inappropriate Medication Use in Older Adults, Arch. Internal Medicine, 2003, 2716 - 2724

TABLE 3 COMMON MEDICATION / MEDICATION INTERACTIONS IN LONG TERM CARE

MEDICATION 1	MEDICATION 2	IMPACT
Warfarin (Coumadin)	NSAIDs such as ibuprofen, naproxen, and COX-2 inhibitors	Potential for serious gastrointestinal bleeding
Warfarin (Coumadin)	Sulfonamides such as trimethoprim/sulfamethoxazole (Bactrim)	Increased effects of warfarin with potential for bleeding
Warfarin (Coumadin)	Macrolides such as clarithromycin (Biaxin), erythromycin	Increased effects of warfarin with potential for bleeding
Warfarin (Coumadin)	Fluoroquinolones such as ciprofloxacin (Cipro), levofloxacin (Levaquin), ofloxacin (Floxin)	Increased effects of warfarin with potential for bleeding
Warfarin (Coumadin)	phenytoin (Dilantin, Phenytek)	Increased effects of warfarin and/or phenytoin
ACE Inhibitors such as benazepril, captopril, enalapril, and lisinopril	Potassium Supplements	Elevated serum potassium levels
ACE Inhibitors such as benazepril, captopril, enalapril, and lisinopril	spironolactone (Aldactone)	Elevated serum potassium levels
digoxin (Lanoxin)	Amiodarone (Cordarone, Pacerone)	digoxin toxicity
digoxin (Lanoxin)	verapamil (Calan, Covera-HS, Isoptin)	digoxin toxicity
Theophylline	Fluoroquinolones such as ciprofloxacin (Cipro), levofloxacin (Levaquin), ofloxacin (Floxin)	theophylline toxicity

SOURCE: American Society of Consultant Pharmacists & American Medical Directors Association. Top 10 Dangerous Drug Interactions in Long-Te... ar... esented by the Mu... isciplinary Medication Management (M3) Project.

TABLE 4 CARE AREA ASSESSMENTS (CAAs)

1. Delirium	8. Mood State	15. ...n... Care
2. Cognitive Loss/Dementia	9. Behavioral Symptoms	16. P... su... lcer
3. Visual Function	10. Activities	17. P... chotr... ... Use
4. Communication	11. Falls	18. ...ysical Re... aints
5. ADL Functional/Rehabilitation Potential	12. Nutritional Status	1... Pain
6. Urinary Incontinence and Indwelling Catheter	13. Feeding Tube	20. Return to Community Referral
7. Psychosocial Well-Being	14. Dehydration/Fl... Maintenanc...	

The information contained herein is designed to serve as a guide. The information is correct to the best of the knowledge of the developers. It is the responsibility of health care professionals to use their professional judgement for safe and effective drug therapy.

Medication Regimen Review (MRR) Forms from MED-PASS

MED-PASS MRR forms reflect the significant growth of the role and responsibilities of the consultant pharmacist relative to the long-term care resident as a result of the expansion of the federal unnecessary medication regulations released for implementation in December 2006. The completely updated MRR forms are designed to provide the pharmacist with a systematic and comprehensive medication regimen review process.

Additionally, the MRR forms have been updated to reflect MDS 3.0 with the replacement of RAPs (Resident Assessment Protocols) with (CAAs) Care Area Assessments which identify special health risk areas such as pressure ulcers and falls.

These MRR forms reflect the new guidelines by:

(1) integrating with the multidisciplinary plan of care;

(2) utilizing and documenting an assessment of the resident through the MDS Care Area Assessments, and;

(3) moving beyond the historical focus on psychoactive medications to focus on any potential medication irregularity related to:

a. multiple medication classes (alone or in combination with certain disease states) known to pose risks to the elderly;

b. medication interactions common to long term care;

c. medications with FDA warnings relevant to the elderly, and;

(4) including, for the first time, additional focus on pharmacist-recommended interventions (med and non-med) when clinical situations warrant.

The new MRR forms include:

- Review Criteria Section that details:
  - Potential Medication Irregularities
  - Situation(s) Needing Possible Medication Intervention
  - Situation(s) Needing Possible Non-Pharmacological Intervention
- MRR Documentation/Physician Notification Section
- Reference Section that contains tables from the Federal Regulations plus an additional table that list MDS CAAs

How to use the new MRR forms

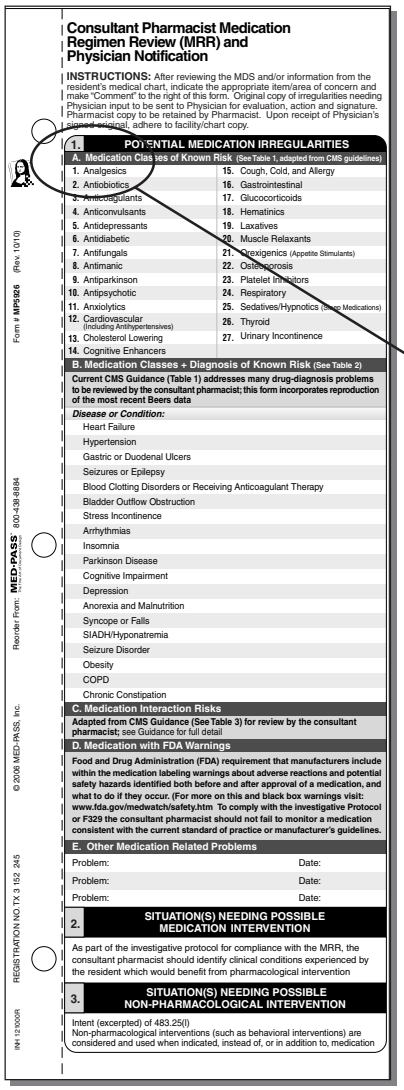
The consultant pharmacist begins the MRR process by reviewing the resident's current clinical condition and assessing the resident. The previous focus on medical, nursing and laboratory information has been expanded to the collection of assessment information from additional multidisciplinary sources including triggered CAAs.

Collecting the Resident Assessment Information – suggested steps for the pharmacist

1. Upon each visit to the nursing facility, ask for a list of residents who have had a Significant Change of Status MDS performed. Determine the precipitating reason for the functional or clinical change in the resident's status, then review the medication regimen for a possible cause.
2. Request a list of residents that have been admitted to the hospital or that have had an emergency room visit since you last reviewed their medication regimen
3. Compare the resident's two most recent MDS assessments. This will indicate an improvement or decline in the resident's clinical, physical, emotional, or social well-being. In any case, the medication regimen – especially newly prescribed drugs – should be evaluated as a possible cause.

MRRsFly 12/10

Review Criteria Section (Illustration #1)



Consultant Pharmacist Medication Regimen Review (MRR) and Physician Notification

INSTRUCTIONS: After reviewing the MDS and/or information from the resident's medical chart, indicate the appropriate item/area of concern and make "Comment" to the right of this form. Original copy of irregularities needing Physician input to be sent to Physician for evaluation, action and signature. Pharmacist copy to be retained by Pharmacist. Upon receipt of Physician's signed original, adhere to facility/chart copy.

1. POTENTIAL MEDICATION IRREGULARITIES

A. Medication Classes of Known Risk (See Table 1, adapted from CMS guidelines)

1. Analgesics	15. Cough, Cold, and Allergy
2. Antiobiotics	16. Gastrointestinal
3. Anticoagulants	17. Glucocorticoids
4. Anticonvulsants	18. Hematinics
5. Antidepressants	19. Laxatives
6. Antidiabetic	20. Muscle Relaxants
7. Antifungals	21. Orexigenics (Appetite Stimulants)
8. Antimanic	22. Osteoporosis
9. Antiparkinson	23. Platelet Inhibitors
10. Antipsychotic	24. Respiratory
11. Anxiolytics	25. Sedatives/Hypnotics (Sleep Medications)
12. Cardiovascular (Including Antihypertensives)	26. Thyroid
13. Cholesterol Lowering	27. Urinary Incontinence
14. Cognitive Enhancers	

B. Medication Classes + Diagnosis of Known Risk (See Table 2)

Current CMS Guidance (Table 1) addresses many drug-diagnosis problems to be reviewed by the consultant pharmacist; this form incorporates reproduction of the most recent Beers data

Disease or Condition:

Heart Failure
Hypertension
Gastric or Duodenal Ulcers
Seizures or Epilepsy
Blood Clotting Disorders or Receiving Anticoagulant Therapy
Bladder Outflow Obstruction
Stress Incontinence
Arrhythmias
Insomnia
Parkinson Disease
Cognitive Impairment
Depression
Anorexia and Malnutrition
Syncope or Falls
SIADH/Hyponatremia
Seizure Disorder
Obesity
COPD
Chronic Constipation

C. Medication Interaction Risks

Adapted from CMS Guidance (See Table 3) for review by the consultant pharmacist; see Guidance for full detail

D. Medication with FDA Warnings

Food and Drug Administration (FDA) requirement that manufacturers include within the medication labeling warnings about adverse reactions and potential safety hazards identified both before and after approval of a medication, and what to do if they occur. (For more on this and black box warnings visit: www.fda.gov/medwatch/safety.htm To comply with the investigative Protocol or F329 the consultant pharmacist should not fail to monitor a medication consistent with the current standard of practice or manufacturer's guidelines.

E. Other Medication Related Problems

Problem: Date:
Problem: Date:
Problem: Date:

2. SITUATION(S) NEEDING POSSIBLE MEDICATION INTERVENTION

As part of the investigative protocol for compliance with the MRR, the consultant pharmacist should identify clinical conditions experienced by the resident which would benefit from pharmacological intervention

3. SITUATION(S) NEEDING POSSIBLE NON-PHARMACOLOGICAL INTERVENTION

Intent (excerpted) of 483.25(l)
Non-pharmacological interventions (such as behavioral interventions) are considered and used when indicated, instead of, or in addition to, medication

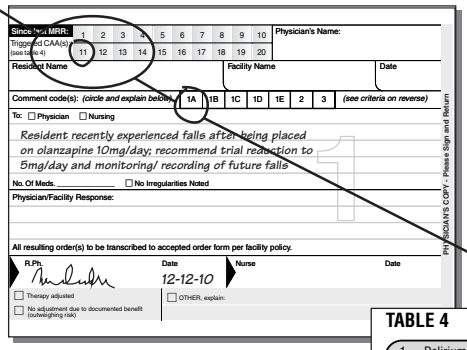
Form # MP5926 (Rev. 10/10) Reorder From: MED-PASS® 800-438-8884 © 2006 MED-PASS, Inc. REGISTRATION NO.:TX 3 152 245 IN# 123008

Completing the MRR form

Using the information collected, the pharmacist should look for any potential medication irregularities that may be related to known risk areas that are listed in the federal regulations and are printed in the Review Criteria Section **(Illustr. #1)** of the MRR form.

The pharmacist would then note in the documentation section **(Illustr. #2)** of the MRR the source of the assessment information indicating a clinical or functional change – a triggered CAA.

(Illustration #2)



Since last MRR: 1 2 3 4 5 6 7 8 9 10
Triggered CAA(s) (see table 4): 11 12 13 14 15 16 17 18 19 20
Physician's Name:
Resident Name | Facility Name | Date
Comment code(s): *(circle and explain below)* 1A 1B 1C 1D 1E 2 3 *(see criteria on reverse)*
To: ☐ Physician ☐ Nursing
Resident recently experienced falls after being placed on olanzapine 10mg/day; recommend trial reduction to 5mg/day and monitoring/ recording of future falls
No. Of Meds. _____ ☐ No Irregularities Noted
Physician/Facility Response:
All resulting order(s) to be transcribed to accepted order form per facility policy.
R.Ph. | Date 12-12-10 | Nurse | Date
☐ Therapy adjusted
☐ No adjustment due to documented benefit (outweighing risk)
☐ OTHER, explain:
PHYSICIAN'S COPY - Please Sign and Return

EXAMPLE: If the Falls CAA was triggered and the resident was recently placed on an antipsychotic agent, the pharmacist should circle "11" (see reference Table 4 for a list of the CAAs) on the documentation section **(Illustr. #2)**.

TABLE 4 CARE AREA ASSESSMENTS (CAAs)

1. Delirium	8. Mood State
2. Cognitive Loss/Dementia	9. Behavioral Symptoms
3. Visual Function	10. Activities
4. Communication	11. Falls
5. ADL Functional/Rehabilitation Potential	12. Nutritional Status
6. Urinary Incontinence and Indwelling Catheter	13. Feeding Tube
7. Psychosocial Well-Being	14. Dehydration/Fluid Maintena

Also, the pharmacist should circle Comment Code "**1A**" which correlates to "**1. Potential Medication Irregularities**" and "**A. Medication Classes of Known Risk**" under which **Antipsychotic** is listed in the Review Criteria Section **(Illustr. #1)**.

Next, the pharmacist should write a narrative as to his findings and recommendation(s) such as: *"Resident recently experienced falls after being placed on olanzapine 10mg/day; recommend trial reduction to 5mg/day and monitoring/recording of future falls",* complete any other areas deemed relevant to the irregularity and sign/date the form.

(**NOTE** for MP5926: the documentation section is a multi-part slip that can be detached with the original being routed to the physician and the copy to the pharmacist.)

MRR Forms Overview:

MP5926 Accommodates one resident for up to three monthly reviews. Detachable Physician Notification slip can be sent to physician, and the signed copy adhered to chart copy (via adhesive tape) to complete the physician review request/physician review response cycle. Works like a "telephone order".

MP5905 Accommodates one monthly review for up to five residents on one form.

To view each of these forms visit **www.med-pass.com** and enter the form number in the "SEARCH" box.

MRRsFly 12/10

Date of Report

MEDICATION ERROR REPORT

DESCRIPTION OF ERROR

Date of error | Time of error ☐ AM ☐ PM | Medication as ordered

Description of error (include medication, dose, route and time administered)

Outcome to resident and care provided

Physician notified? ☐ No ☐ Yes | Name | Date | Time ☐ AM ☐ PM
If no, explain

GM/AL Mgr/Administrator notified? ☐ No ☐ Yes | Name | Date | Time ☐ AM ☐ PM
If no, explain

Pharmacy notified? ☐ No ☐ Yes | Name | Date | Time ☐ AM ☐ PM
If no, explain

Family/Responsible Party notified? ☐ No ☐ Yes | Name | Date | Time ☐ AM ☐ PM
If no, explain

SUMMARY OF ERROR

Type of Error

- ☐ Wrong dose
- ☐ Wrong route
- ☐ Wrong medication
- ☐ Wrong time
- ☐ Wrong dosage form
- ☐ Drug ordered but not administered (at least once)
- ☐ Drug administered without physician's order
- ☐ Failure to follow manufacturer specifications and/or accepted professional standards
- ☐ Other

Reason for Error

- ☐ Transcription error
- ☐ Misread error
- ☐ Miscalculated dose
- ☐ Mismeasured dose
- ☐ Failure to identify resident
- ☐ Pharmacy error
- ☐ Self medication error
- ☐ Poor lighting/environment

Corrective action taken

Measures taken to prevent recurrence

(Per Facility Policy)	Signature	Title	Date
Person making error			
Person reporting error			
Attending physician			
Pharmacist			
AL Mgr/Administrator			
Director of Health Services (if applicable)			
General Manager (if applicable)			

Resident Name	Clinical Record #	Room #	Physician

Reorder From MED-PASS 800-436-8984 Form # CP1805 03/04 INB651104

MEDICATION DISCREPANCY REPORT

Directions: To be completed by nurse responsible for medication discrepancy or by nurse who discovers the discrepancy.

Date of Discrepancy	Time of Discrepancy
	☐ AM ☐ PM

Check items that are applicable:

- ☐ 1) Omission (drug ordered but not administered at least once)
- ☐ 2) Unauthorized Drug (drug administered without a physician's order)
- ☐ 3) Wrong Dose
- ☐ 4) Wrong Route of Administration
- ☐ 5) Wrong Dosage Form
- ☐ 6) Wrong Drug
- ☐ 7) Wrong Time
- ☐ 8) Failure to Follow Manufacturer's Specifications and/or Accepted Professional Standards
- ☐ 9) Other: _____

Answer YES or NO:

	YES	NO
1. Was the order written correctly?	☐	☐
2. Did you follow the THREE RULES?	☐	☐
- LOOK at the medicine as you removed it from the cart?		
- COMPARE it with the MAR?		
- LOOK at it as you replaced it in the cart?		
3. Was the order plainly written?	☐	☐
4. Was the order transcribed onto the MAR properly?	☐	☐
5. Was the environment and lighting (well lit) conducive to pouring medications?	☐	☐
6. Did pharmacy provide the correct medication and labeling?	☐	☐
7. Did pharmacy place proper auxiliary label on prescription?	☐	☐
8. Was attending physician notified? If Yes: Date _____ Time _____	☐	☐
9. Was family or responsible party notified? If Yes: Date _____ Time _____	☐	☐

Describe the incident (include medication, dose, route and time administered)

Outcome to resident (provide factual comparison of resident before and after incident)

Corrective action taken

Measures taken to prevent recurrence

Physician's response

Name of Nurse Responsible for Medication Discrepancy	Number of residents to whom medications were given:

SIGNATURES *(as required by facility)*

Signature of Nurse Completing Report	Date	Signature of Attending Physician	Date
Signature of DON	Date	Signature of Medical Director	Date
Signature of ☐ Consultant Pharmacist ☐ Risk Manager	Date	Signature of Administrator	Date

Resident Name	ID #	Room #	Physician

WHITE - Director of Nursing/Nursing Supervisor YELLOW - R.Ph. Consultant

INSTRUCTIONS FOR USE: Medication reconciliation is a formal process of obtaining a complete and accurate list of each patient's current medications (including name, dosage, frequency and route) and comparing the incoming admission, transfer, and/or discharge medication orders to that list. Discrepancies are brought to the attention of the prescriber and, if appropriate, changes are made to the orders. Any resulting changes in orders are documented. Use this form to list all prescription, non-prescription (OTC), herbal/vitamin medications, patches and inhalers either taken routinely or on an as needed (PRN) basis. File according to facility policy.

MEDICATION RECONCILIATION FORM

☐ Quality Assurance ☐ Admit/Readmit

Facility Name:			Resident/Patient Name:	Date of Birth:
Admitted From:	Admission Date:	Time:	Allergies:	

LIST ALL MEDICATIONS IDENTIFIED (reported by family, patient, med bottles, include dose, frequency, route and PRN medications)					DATE AND TIME OF LAST DOSE (IF AVAILABLE)	DATA SOURCE*	Do all medication records match? Y = Yes N = No			If "No", which element requires review?				Outcome of review discrepancy (orders written on physician order sheet)			Is there an indication in dc summary to support med ordered?		If "No", seek info from providers in hospital, community, physician, family, patient & document diagnosis or rationale on order sheet
MEDICATION NAME	DOSE	FREQ.	ROUTE	✓ IF PRN			DC SUMMARY	ADMITTING ORDERS	PREVIOUS MAR	MEDICATION	DOSE	FREQUENCY	ROUTE	CONTINUE ORDER	DISCONTINUE ORDER	MODIFY ORDER	Yes	No	

***DATA SOURCE:** *use one of the following numbers to specify the source of information for each medication*

1A - Prescription from _____ (Pharmacy) _____ (Phone)
1B - Prescription from _____ (Pharmacy) _____ (Phone)
2A - Contact with previous primary care physician(s) _____ (Name) _____ (Phone)
2B - Contact with previous primary care physician(s) _____ (Name) _____ (Phone)
3 - Documentation from referring facility (e.g. hospital discharge summary, LTCF transfer form, etc.)
4 - Resident/family member statement
5 - Other (specify) _____
6 - Other (specify) _____

FORM COMPLETED BY: Signature:	Title:	Date	Time:

MEDICATION REGIMEN REVIEW (MRR) REQUEST NOTIFICATION

*Please notify the pharmacy if the resident is expected to stay in the facility for less than 30 days, has a change of condition, or any other circumstance where a **Medication Regimen Review (MRR)** should be conducted. The pharmacy will provide a Medication Regimen Review after this notification is received. Fax completed form to pharmacy/consultant pharmacist and file in chart with consultant pharmacist reviews, or according to facility policy.*

Facility Name:

Resident Name: | **Physician Name:**

Allergies:

Diagnosis:

DOB: | **Weight:** | **Height:** | **BP:** | **Pulse:**

REASON FOR REQUEST

- ☐ Short Term Stay _____ Anticipated Discharge Date _____
- ☐ Significant Change in Condition _____
- ☐ Other _____

CLINICAL DESCRIPTION OF NEED FOR REVIEW *(Please check all that apply and explain)*

- ☐ Anorexia and/or unplanned weight loss, or weight gain: _____
- ☐ Behavioral changes, unusual behavior patterns (including increased distressed behavior): _____
- ☐ Bowel function changes including constipation, ileus, impaction: _____
- ☐ Confusion, cognitive decline, worsening of dementia (including delirium) of recent onset: _____
- ☐ Dehydration, fluid/electrolyte imbalance: _____
- ☐ Depression, mood disturbance: _____
- ☐ Dysphagia, swallowing difficulty: _____
- ☐ Excessive sedation, insomnia, or sleep disturbance: _____
- ☐ Falls, dizziness, or evidence of impaired coordination: _____
- ☐ Gastrointestinal bleeding: _____
- ☐ Headaches, muscle pain, generalized aching or pain: _____
- ☐ Rash, pruritus: _____
- ☐ Seizure activity: _____
- ☐ Spontaneous or unexplained bleeding, bruising: _____
- ☐ Unexplained decline in functional status (e.g. ADLs, vision): _____
- ☐ Urinary retention or incontinence: _____
- ☐ Other: _____

Please be specific and describe change in condition

Please also fax to pharmacy any information that helps in the evaluation of the individual's record *(MARs, MD Notes, Hospital Discharge/Transfer Form, Nursing Notes, Labwork, etc.)*

Total # of pages faxed _____
(including this form and fax cover sheet)

Person Reporting Request: *Name/Title* | **Date of request:**

PHARMACY / CONSULTANT USE ONLY

FAX COMPLETED FORM AND SUPPORTING DOCUMENTATION TO PHARMACY/CONSULTANT PHARMACIST

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

Report From February 23, 2012, Pharmaceutical Compliance Roundtable

Introduction

On February 23, 2012, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) convened a Government-industry Pharmaceutical Compliance Roundtable. The Roundtable provided an opportunity for OIG to discuss with compliance professionals in the pharmaceutical industry their experiences under Corporate Integrity Agreements (CIAs) and with various types of compliance activities. One goal of the Roundtable was to identify compliance measures that participants find effective and share these with others within and beyond the pharmaceutical industry.

Forty-two compliance officers and other compliance professionals from 23 pharmaceutical manufacturers currently under CIAs attended the day-long event. The Roundtable consisted of large and small group sessions. During the small group sessions, industry representatives engaged in dialogue with more than 15 representatives from the Office of Counsel to the Inspector General, including several CIA monitors for the companies in attendance. While OIG gained valuable insights, the participants understood that the Roundtable was an opportunity to exchange information and that existing CIAs would not be renegotiated on the basis of their comments.

The Roundtable began with a large group session during which Inspector General Daniel Levinson and Chief Counsel Lewis Morris delivered introductory remarks. The large group then divided into smaller breakout sessions. During the day, all attendees discussed each of these five topics: (1) Challenges in Implementing CIAs; (2) Compliance Program Structure and Oversight; (3) Risk Assessment and Monitoring Activities; (4) Policies, Procedures, and Training Activities; and (5) Compliance Post-CIA.

Teams of OIG representatives functioned as moderators and scribes for each breakout session. At the end of the day, the moderators highlighted some of the issues discussed in their respective groups. A summary of those discussions is set forth below.

Topic 1: Challenges in Implementing CIAs

Participants discussed issues related to challenges in implementing CIA requirements. The primary issues were: (1) the definition of "Relevant Covered Person," (2) the deadlines for the initial implementation of CIA requirements, (3) training requirements, (4) the health care provider (HCP) notice letter, (5) payment-posting requirements, and (6) working with Independent Review Organizations (IROs). Participants described their experiences in implementing the CIAs and recommended changes to CIAs.

Definition of "Relevant Covered Persons": CIAs require that companies provide specified written policies and procedures and training to individuals who meet the CIA definition of "Relevant Covered Persons." Participants reported that their companies interpret the definition broadly and that this creates challenges in correctly identifying all Relevant Covered Persons. Some participants reported that the broad definition may cause companies to train categories of employees (*e.g.*, manufacturing and research personnel) for whom the training may not be directly relevant to their daily job responsibilities. Participants expressed concern that such training may undermine compliance credibility if training does not seem meaningful.

Some participants reported that it is particularly challenging to correctly identify Relevant Covered Persons who are contractors. Participants suggested that OIG narrow the definition of "Relevant Covered Persons" so that it includes only contractors who interact directly with HCPs or consumers or who create promotional or product-related materials that could be used externally without first receiving internal company review. Another challenge identified by participants was training for contractors who provide services to more than one company. This issue is discussed below as part of Topic 4.

Deadline for initial implementation of CIA requirements: CIAs typically require companies to develop and implement codes of conduct, policies and procedures, and training within specific timeframes following the effective date of the CIAs. Participants expressed concern that the timeframes are too short to allow for effective development of company-specific policies, procedures, and training materials. Participants reported that as a result, their companies may use "generic" policies, procedures, and training materials to meet the CIA deadlines for initial implementation. Participants recommended that to allow for development of more meaningful and effective policies, procedures, and training, CIA deadlines be extended.

Training requirements: CIAs require companies to certify that they have trained all Relevant Covered Persons. Participants reported that these requirements cause companies to develop and implement computer-based training modules for which completion is easier to track. While participants believe that small group training (such as that provided during in-person sales meetings) is more effective than computer-based training, attendance at such training may be difficult (and labor-intensive) to track. Some

participants suggested that OIG modify CIA requirements to allow for less than 100-percent completion of training or to permit companies to certify that training sessions were held and that managers are responsible for ensuring attendance.

CIAs also require companies to provide a specified number of hours of training annually about topics outlined in the CIAs. Some participants reported that requirements to provide a specified number of hours of training cause companies to provide repetitive training from year to year that is not focused on new developments or different topics. Participants offered several suggestions to improve training. These included: (1) permitting companies to develop more flexible training plans (especially after the initial reporting period of the CIA) that would be approved by the CIA monitor annually; (2) permitting general training requirements to be satisfied through competency testing (in such cases, employees who pass a compliance test would be exempted from additional training requirements for the year); and (3) revising CIA requirements to allow companies to satisfy CIA obligations with training tailored to identified risk areas.

Notice to health care providers: Some CIAs require companies to send to HCPs a letter briefly describing the terms of the settlement between the Government and the company and the alleged misconduct at issue. Some participants reported that sending this letter is expensive and that it is not an effective vehicle to promote awareness of compliance issues among HCPs. Some participants recommended that if CIAs continue to include this requirement, OIG permit more flexibility in how the content of the letter is delivered. Suggested alternatives were: (1) hand delivery of the letter by sales representatives; (2) posting the pertinent information on a company Web site; or (3) sending the letter by less expensive means (*e.g.*, by regular mail or email) than required by the CIA.

Payment-posting requirements: Certain CIAs require companies to track and post on company Web sites information about payments made by the companies to HCPs. The representatives of companies with these CIA requirements generally agreed that the payment-posting requirements are expensive and time consuming to implement. The physician payment "sunshine" requirements of the Affordable Care Act (ACA) obligate manufacturers to report to HHS information about payments to HCPs. The information will be posted on the HHS Web site. The ACA requirements are somewhat different from the CIA requirements. Participants expressed concern about the differences between, and possible inconsistencies in, the CIA requirements and those in the ACA. Some participants requested that OIG permit companies to satisfy CIA requirements by certifying that they complied with the ACA provisions. Others requested that OIG suspend or alter the transparency requirements in CIAs after the ACA transparency regulations are finalized.

Working with Independent Review Organizations: CIAs with pharmaceutical manufacturers require that companies annually retain outside IROs to conduct reviews of specified items and systems. Participants reported that their companies devote significant compliance resources to educating the IROs about company-specific systems and processes and supporting the IROs during CIA reviews. Some questioned the value of the findings and recommendations from the IROs, especially if identified errors are immaterial or technical in nature. Some participants suggested that a "big picture" compliance review would be more helpful than multiple transaction reviews. Others suggested that to increase the utility of the IRO reviews, CIAs permit more flexibility in IRO reviews and allow, for example, changes in the focus of the IRO reviews in the second year and later years of the CIA.

Topic 2: Compliance Program Structure and Oversight

These sessions focused on two main topics: (1) boards of directors' oversight of, and participation in, compliance-related activities, and (2) integration of compliance activities into business functions beyond the compliance department. Participants uniformly agreed that it is critical for boards of directors to be involved in compliance oversight and that the integration of compliance efforts into business activities materially enhances compliance effectiveness.

Involvement of Boards of Directors in Compliance-Related Activities

Participants provided these examples of many ways in which boards of directors are involved in compliance: (1) review and oversight of audits and identified risks, (2) review of compliance issues pertaining to particular business initiatives, (3) periodic interaction with compliance officers and with third-party compliance experts who may assess the company's compliance program, (4) board training and education, (5) compliance-related certifications and the passage of compliance-related resolutions, and (6) general assessments of the company's compliance program. Participants recommended that boards of directors and company management convey messages about the value and importance of compliance (including as a competitive business advantage). Participants also observed that when compliance officers routinely make reports to their companies' boards, this activity underscores the importance of compliance.

Board resolutions and certifications: Some CIAs require that board members annually pass and sign a resolution confirming, if they can, that the company has implemented an effective compliance program. Participants reported that these requirements lead board members to better understand compliance issues and ask more questions about compliance (and their own potential liability). Certain CIAs require that boards retain outside compliance experts to independently assess the company's compliance program. Participants reported that board experiences with compliance experts have been positive. Some participants recommended that boards engage such

experts even if not required by a CIA. Many participants reported that their boards view compliance officers as respected, informed compliance resources. Some participants noted there is a process for gaining such respect. Participants acknowledged there are challenges in evaluating and measuring compliance. They recommended that compliance metrics be articulated in a way designed to motivate compliance and discourage noncompliance.

Organizational structure issues: CIAs require the appointment of compliance officers who are members of senior management and are not subordinate to the general counsel or the chief financial officer. Participants reported that they have found this structure to be beneficial. Some participants noted that some companies not under CIAs continue to make compliance officers subordinate to general counsels and suggested that OIG clarify (or reiterate) the risks associated with this type of reporting structure.

Some participants opined that the CIAs did not adequately account for differences in the organizational and oversight structures of companies. These differences may arise, in part, because of the national or international nature of the company (including whether there are national and/or international boards) and whether the company is publicly traded or privately held. Participants recommended that OIG take into account these differences and consider: (1) more flexible approaches to board training requirements and (2) flexibility in IRO and compliance expert review requirements.

Integration Into and Coordination Between Compliance and Business Operations

Participants uniformly agreed that integration of compliance into a company's broader business operations greatly enhances the effectiveness of compliance programs. Participants reported that their companies accomplish this integration by, among other things, locating compliance personnel and resources at headquarters and using training, communications, technology, and compliance personnel and field-based managers to disseminate compliance messages and activities to the field.

Examples of compliance/business integration: Reported examples of the integration of compliance and business functions include: (1) appointing deputy compliance officers within individual business units; (2) requiring business unit managers to incorporate compliance considerations in business decisionmaking; (3) increasing individual accountability by requiring compliance-related certifications from senior management in key business units; (4) imbedding compliance representatives (sometimes called liaisons, ambassadors, or champions) in individual business units; (5) including compliance-related requirements as an element in performance plans of all employees; (6) staffing compliance committees with individuals from varied business units and disciplines; and (7) fostering lines of communication between headquarters compliance staff and business unit personnel, including through monitoring of field activities by headquarters staff.

Business "ownership" of compliance: Participants recommended that to the extent possible, business units "own" compliance. Participants suggested this could be accomplished by: (1) educating business unit managers about compliance so that they understand and can identify relevant compliance risks, (2) ensuring that business unit policies and procedures incorporate compliance elements, (3) requiring business unit personnel to deliver periodic compliance training, and (4) proactively incorporating compliance considerations into business decisionmaking and business initiatives. Participants stressed the importance and efficiency of the last point and suggested that it could be accomplished, in part, by including compliance personnel as part of the business team rather than as a separate unit. Participants noted that increased coordination between compliance and business functions can lead to increased opportunities for cross-functional usage of data (*e.g.,* information available to the company through compliance assessments may be useful for business units) and underscore business benefits that can come from compliance activities.

Challenges to compliance and business integration: Participants noted several challenges to integrating compliance into business functions. Frequent changes at pharmaceutical companies are one such challenge. Companies routinely experience turnover of personnel and changes in product portfolio. Participants recommended that their companies be vigilant about compliance in the face of such changes. Increased outsourcing to third-party vendors was identified as another challenge. Participants suggested that companies establish lines of communication and appropriate verification and oversight processes with their vendors. Finally, participants identified as another challenge the development of meaningful and appropriate training. Training is discussed in more detail below, but participants generally stressed the need for personnel from compliance, human resource, information technology, and other components to understand the importance of compliance, understand their respective responsibilities, and have good working relationships in order to design and implement effective compliance programs and training initiatives.

Topic 3: Risk Identification and Monitoring Activities

These sessions focused on risk-assessment processes and methods by which companies conduct internal monitoring. While most CIAs do not explicitly require companies to engage in a specific process to identify compliance risks, most participants indicated that their companies routinely engage in a variety of risk-assessment activities. Many CIAs require companies to monitor specified types of activities during each year of the CIA (through internal programs and/or IROs). Participants commented on various types of monitoring activities and recommended that CIAs allow for increased flexibility with regard to required monitoring activities.

Risk-Assessment Practices

Participants widely reported that their companies engage in multiple types of risk-assessment activities, including those at a companywide level, on a product-specific basis, or both. Participants observed that the types of risk assessments that are effective for one company may not be effective for another company.

Participants reported that compliance training for management and field representatives is essential to an effective risk-identification program because it enables individuals "in the business" to better identify compliance risks and take appropriate mitigation steps. In addition, participants reported that if compliance personnel have "a seat at the table" when sales and marketing activities are planned or discussed, they can help ensure that risks are preemptively identified and addressed.

Monitoring Activities

Many CIAs require companies to annually monitor a specified set of activities. Required monitoring activities include reviews of: (1) sales representative call notes; (2) the activities of the medical information department (including responses to inquiries about off-label uses of drugs); and/or (3) speaker program activities. Several CIAs also require that compliance personnel "ride along" with field representatives on sales calls to HCPs. In addition, several CIAs require key managers to certify that the business units for which they are responsible are compliant with legal, CIA, and company standards.

Flexibility in monitoring: As a general comment, many participants requested that OIG permit greater flexibility under CIAs to monitor new or different activities in later years of a CIA. Participants asserted that the monitoring obligations of CIAs can be focused on past conduct and that by the time a CIA is implemented, the company has likely identified new risk areas (*e.g.*, as a result of risk-assessment or auditing practices) to which oversight resources would be better deployed. In addition, the risks for a company evolve during the term of the CIA. Some participants also suggested that companies be relieved of certain obligations in the later years of the CIA if they are able to demonstrate compliance with CIA requirements and positive results through auditing and monitoring.

Identity of monitors: Some CIAs require that certain monitoring activities be undertaken by compliance department personnel only. Participants requested that CIAs permit more extensive use of outside consultants or company employees from outside the compliance department in conducting auditing and monitoring activities. This would allow companies to deploy their limited compliance resources for collaborative and educational purposes. To address concerns about the qualifications of noncompliance personnel to conduct such monitoring, participants suggested that consultants and internal

staff be extensively trained and that their work be subject to oversight by compliance personnel.

Compliance messaging: Participants stressed the importance of ongoing messaging and communication about compliance as a way to enhance risk-assessment and monitoring activities. Participants recommended that companies disseminate compliance messages from a variety of sources. For example, participants suggested that compliance messages be delivered by senior, district, and regional managers; during in-person meetings with sales representatives; during various auditing and training interactions; at business unit meetings; and through bulletins from the human resources department.

Call note review: Participants reported that their companies consistently review call notes as a means to monitor activities of sales representatives. Participants noted the variability among the call note systems. Some companies use a free-text call note system (which essentially permits representatives to record their notes without limitations in a "free text" system), while other companies use a system of drop-down menus containing preset descriptors with which sales representatives may populate their call notes. Some participants noted that the drop-down systems permit a relatively simple categorization of information from call notes that may be used for multiple compliance and business-related purposes. Other participants noted that the free text systems may allow for more accurate and clear descriptions of the interactions with HCPs.

Monitoring of medical information: Some participants reported that ongoing reviews of medical information department activities yielded diminishing compliance returns in the later years of a CIA. Many participants reported that their medical information functions had strong control systems in place prior to the CIAs and that their systems do not benefit materially from additional CIA oversight.

Speaker programs: CIAs require compliance or other personnel to attend speaker programs in order to conduct "live" monitoring of the programs. Some participants recommended that the CIAs permit the monitoring of speaker programs or other events via teleconference or videoconference. This would reduce costs associated with deploying headquarters-based compliance personnel to attend programs throughout the country.

Ride-along activities: Participants reported mixed results from compliance personnel ride-alongs with sales representatives. Many participants reported that such ride-alongs do not generally lead to the identification of specific noncompliant conduct by sales representatives. However, participants widely agreed that these activities are beneficial because they establish a line of communication between field and compliance personnel and enable the development of relationships between the two groups. Some participants recommended that CIAs allow more flexibility in how companies engage in

these sorts of beneficial "relationship-building" activities (*e.g.,* through compliance personnel participation in regional sales meetings or trainings).

Most CIAs do not require that district managers (or other supervisors in a sales representative's chain of command) conduct ride-alongs. However, participants reported that such activities are common and effective and consistently yield information useful to both compliance and the business units. Participants believe that these ride-alongs are effective because the managers work closely with field personnel on a regular basis and understand issues faced by sales representatives. According to some participants, their companies incorporate compliance metrics into supervisory ride-alongs and district managers are expected and required to report on, and educate their subordinates about, noncompliant behavior. Finally, some participants reported that senior management and members of their boards of directors have sought opportunities to conduct field visits or attend national sales meetings to enhance their understanding of the day-to-day work of field representatives.

Management certifications: Participants favor the inclusion of certification requirements for board members and managers in CIAs because they lead to deeper levels of involvement in compliance activities. Participants uniformly found that such certifications cause board members and managers to ask questions about compliance and take ownership of compliance.

Topic 4: Policies, Procedures, and Training Activities

CIAs require that companies establish written policies and procedures related to the business operations of the company (*e.g.,* sales, marketing, and interactions between companies and HCPs). CIAs also require companies to provide general training and job-function-specific training to persons covered by the CIA. Participants offered insights about the development and dissemination of policies and procedures and training activities at their companies.

Policies and Procedures

Development and revision of policies and procedures: Participants uniformly recommended that to generate the most effective policies and procedures, business unit personnel and other affected stakeholders participate in the development and revision process. In most companies, participants noted that compliance officers or other compliance personnel collaborate with business unit personnel to draft and revise policies and procedures. Participants recommended that policies be straightforward and relatively simple to maximize compliance and facilitate the identification of noncompliance. One participant reported that the company's compliance department tested policies by having compliance staff observe policies being implemented in the field and by having field-based employees explain the policies to the compliance staff.

A variety of methods may be used to identify areas for which new or revised policies are appropriate. Some participants reported that companies create or update policies in response to changes in applicable legal requirements or on the basis of newly identified risk areas (such as those identified through an internal investigation). Other participants suggested that issues identified through disclosure programs or raised to compliance personnel may signal a need for policy clarification or revision. According to participants, companies may also periodically review their policies to determine whether each policy is still necessary and appropriately written.

Accessibility and format: Participants agreed widely that policies must be accessible to employees and be provided in a useful format. Different methods may be used to achieve this goal, including technology-based initiatives. Some participants reported that their companies post compliance policies and the code of conduct on an Intranet Web page and provide prominent links between business unit Web pages and the compliance department's Web page. Other companies have reportedly developed specific compliance Web pages for individual business units (*e.g.*, a marketing compliance page) or written compliance products tailored to individual business units (*e.g.*, a compliance guide for the marketing department).

Participants also emphasized the need to make compliance information available in different formats and to permit questions to be asked through various mechanisms. In addition to reporting a compliance department Intranet site and a hotline, some participants reported that their companies established electronic search capabilities that enable employees to search for particular topics within compliance-related documents. Participants reported that some companies have also established electronic mechanisms through which employees may send text or email queries directly to the compliance department and/or legal departments.

Training

Many themes discussed in connection with the implementation of CIAs (summarized above for Topic 1) were repeated during this session. For instance, participants reiterated the challenges in identifying Relevant Covered Persons and meeting CIA deadlines. Participants also raised the concept of competency-based training and requested more flexibility in developing and implementing training.

Effective training: Participants stressed the need for effective training and agreed widely that in-person training tailored to the specific job functions of employees is particularly effective. Participants found the inclusion of specific relevant examples in training (*e.g.,* those based on real-world conduct) to be meaningful. Participants also reported good results from training business unit supervisors and, in turn, having the supervisors provide the training within the business units. Other productive training

activities reported by participants included role-playing activities, competitive games, and the use of a virtual classroom for training staff dispersed across a large area.

Training of contractors: Participants identified unique challenges in training employees of contractors engaged in functions covered under CIAs. Participants reported that they spend a significant amount of time determining which contractors must receive training under the CIAs. Some contractors provide services to one or more companies operating under CIAs and, as a result, have multiple training obligations. Participants suggested that OIG and/or companies under CIAs create baseline training for Relevant Covered Person contractors and permit the completion of the baseline training to satisfy CIA training requirements for all companies. Another variation on the theme was a suggestion that CIAs permit contractors to use certificate-based training. Participants suggested that, under this proposal, a contractor would take OIG-approved training annually. The company under the CIA would then obtain a certification from the contractor confirming the completion of OIG approved-training within the past year, and the company could rely on this certification to fulfill its CIA obligations. However, participants also suggested that if a contractor operates in an area of high compliance risk, the manufacturer under the CIA might nonetheless decide to provide direct training to that contractor to reduce compliance risk.

Topic 5: Compliance Post-CIA

In these sessions, participants were asked to identify which CIA-required compliance measures they would recommend their companies continue after the conclusion of the CIAs. Participants were also asked to predict the biggest compliance risks likely to face their companies and the industry in the next 5 years.

Compliance Measures After the Term of the CIA

Most participants expect that their companies will continue a number of compliance activities following the conclusion of the CIA. However, participants predict that their companies would tailor these measures to the companies' risks and priorities. Specific types of compliance measures likely to be retained included the following:

Certifications and board involvement: Participants expressed wide agreement that management certifications are valuable and would likely be continued. As discussed above, participants find that the certification process promotes compliance throughout the company and generates personal accountability for compliance. Some participants proposed that following the CIA, companies make truthful certifications a condition of employment or a requirement in order to receive a bonus. Participants also predicted that boards would continue to be substantively involved in post-CIA compliance programs and that such involvement would be vital.

Training and disclosure programs: Participants indicated that their companies would continue training efforts but would make the training more flexible and tailor it to their companies' current risks and values. Participants expect that post-CIA training will emphasize quality of training over the number of hours of training. In addition, participants recommended that disclosure programs be continued because they permit employees to raise compliance issues and underscore that every employee has a role in ensuring compliance.

Field monitoring: Participants expect their companies to continue to monitor field-based activities after their CIAs ended. However, participants also suggested that the monitoring likely would become more flexible to focus on current risk areas (which change over time). In light of the widely recognized benefits of relationship-building activities, most participants indicated that their companies would continue to engage in ride-along activities with sales representatives. However, participants also expect their companies to conduct fewer such activities and use other means to monitor the field sales force.

IRO-type reviews: Participants anticipate that their companies will continue to rely on external parties (such as IROs) to conduct reviews, but would do so on a limited basis. Participants predicted that the scope of the reviews would be special projects and work related to current risks. Participants find IROs to be expensive. Some participants believe that internal audits would be equally beneficial.

Predicted Future Compliance Challenges

Participants also identified areas that are expected to present the biggest compliance challenges in the near future. Anticipated challenges include the following:

Changing regulatory and other requirements: Across the board, participants identified their biggest compliance challenge as staying abreast of changing requirements and regulatory complexities, especially in the area of transparency. Many participants cited as an example the requirements relating to the ACA sunshine provisions and the analogous (but different) State reporting requirements. Other participants identified compliance with expanding global requirements (including those in the area of transparency) as a challenge. Finally, participants noted that their companies also face challenges associated with new Government requirements, including those relating to accountable care organizations.

Social media and technology: Participants also identified growing future challenges associated with information about products found on the Internet, including on social media Web sites. This would include information posted by manufacturers as well as other information found on the Internet. Participants voiced a consensus that there is a

lack of clarity and guidance in these areas. They expressed a desire for additional guidance from the Government.

Changing business models: Participants also noted that they face challenges associated with adapting to future changes in their companies and the pharmaceutical industry. Some participants acknowledged ongoing changes in the interactions between their industry and HCPs and expect increased outsourcing of certain functions (such as promotion and research and development). They also emphasized continuing challenges associated with finding qualified staff to undertake compliance activities. Participants underscored the need to maintain flexibility in the face of these changes.

Conclusion

One objective of the Roundtable was to learn more about compliance measures that industry compliance professionals find to be effective. Many of those insights and experiences are reflected in this report. We hope this report will be useful to providers outside the pharmaceutical industry as they seek to enhance their own compliance programs.

OIG received very positive feedback about the Roundtable from participants during the day and following the event. OIG also was pleased with the open and collaborative nature of the dialogue between OIG and industry representatives. While noting that they did not always share OIG's view about certain aspects of CIAs, participants offered valuable feedback about specific CIA provisions and, more generally, about compliance activities. Participants' comments were informative, and OIG will consider them as OIG evaluates provisions for future CIAs. OIG also looks forward to continued positive dialogue with the industry to promote compliance.

OIG GUIDANCE ON IRO INDEPENDENCE AND OBJECTIVITY

Introduction

As a result of the Sarbanes-Oxley Act and an increased focus on issues relating to auditor independence, the OIG issued guidance in 2004 in response to inquiries from individuals and entities subject to Corporate Integrity Agreements (CIAs) regarding circumstances that might affect the independence of an Independent Review Organization (IRO) that performs CIA reviews (e.g., claims reviews, cost report reviews, etc.) for the individual or entity. Since that guidance was issued, the Government Accountability Office (GAO) has updated its auditing standards and CIAs now include additional types of IRO reviews (e.g., arrangements reviews, promotional and product services reviews, etc.). As a result, the OIG has determined that updated guidance in this area is appropriate.

The following is a brief summary of the OIG's views on the relevant principles that should be used to assess the independence and objectivity of an IRO that performs CIA reviews, followed by some examples of situations that likely would and likely would not present independence issues.

Summary of OIG's Views on Applicable Independence and Objectivity Standards

The OIG previously determined that it is appropriate to adopt the standards for auditor independence and objectivity set forth in the GAO *Government Auditing Standards (July 2007 Revision)* (referred to here as the "Yellow Book"). The Yellow Book includes both ethical principles and general standards that apply to all types of IRO reviews performed under CIAs and form the basis of the OIG's requirements relating to the independence and objectivity of the IRO. The Yellow Book principles and standards described below should serve as the basis for determining whether an IRO can provide the required certification as to its objectivity and independence with respect to each CIA review that will be performed by the IRO.[1]

Objectivity

With respect to objectivity, the Yellow Book provides that objectivity includes "being independent in fact and appearance when providing audit and attestation engagements,

[1] CIAs require that each IRO utilized by the provider must furnish a certification that the IRO has evaluated its professional independence and objectivity with respect to the review being performed for the provider and that the IRO has concluded that it is independent and objective. CIAs also give the OIG discretion to reject a provider's choice of IRO or to require a provider to retain a new IRO if the OIG determines that the IRO is not independent.

maintaining an attitude of impartiality, having intellectual honesty, and being free of conflicts of interest."[2] Further, the Yellow Book states that "[a]voiding conflicts that may, in fact or appearance, impair auditors' objectivity in performing the audit or attestation engagement is essential to retaining credibility."[3] These principles should form the basis of an IRO's certification as to its objectivity with respect to a CIA review.

Independence

The Yellow Book standards on auditor independence require that, in all matters relating to the audit work, the audit organization and the individual auditor must be free from personal, external, and organizational impairments to independence, and must avoid the appearance of such impairments of independence.[4] IROs must maintain independence so that their opinions, findings, conclusions, judgments, and recommendations will be impartial and viewed as impartial by the OIG.[5] IROs should avoid situations that could lead the OIG to conclude that the auditors are not able to maintain independence and thus are not capable of exercising objective and impartial judgment on all issues associated with conducting CIA reviews and reporting on the results of those reviews.[6] In making the certification of its independence required under a CIA, the IRO should consider whether there are personal, external, or organizational impairments to independence.[7]

With respect to organizational independence, the Yellow Book includes specific standards that apply when an audit organization agrees to perform nonaudit services for the same client.[8] These standards would apply to IROs that perform CIA reviews and also provide other nonaudit professional services. The standards require the IRO to evaluate whether providing the services creates an independence impairment either in fact or appearance with respect to the entity for which the IRO is performing a CIA review.[9]

According to the Yellow Book, when assessing independence, the two overarching principles that must be considered are that: (i) audit organizations must not provide nonaudit services that involve performing management functions or make management decisions; and (ii) audit organizations must not audit their own work or provide nonaudit services in situations where the nonaudit services are significant or material to the subject

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[2] See GAO-O7-731G, Government Auditing Standards, paragraph 2.10.
[3] Id.
[4] See Government Auditing Standards, paragraph 3.02.
[5] See Government Auditing Standards, paragraph 3.03.
[6] Id.
[7] See Government Auditing Standards, paragraphs 3.07 – 3.30.
[8] See Government Auditing Standards, paragraphs 3.20 – 3.30.
[9] See Government Auditing Standards, paragraph 3.20.

matter of the audits.[10] The Yellow Book includes guidance regarding three categories of nonaudit services: those that do not impair the audit organization's independence, those that require the audit organization to implement supplemental safeguards in order to not impair the audit organization's independence, and those that do impair the audit organization's independence, regardless of the organization's compliance with the supplemental safeguards.[11]

In order to facilitate an IRO's assessment of its independence and objectivity with respect to CIA reviews, the OIG has set forth below some examples of nonaudit services furnished by an IRO to an entity under a CIA that likely would and likely would not present an impairment to the IRO's independence and objectivity with respect to the IRO performing a CIA review for that entity.

Services That Likely <u>Would Not</u> Impair the IRO's Independence and Objectivity:

- IRO personnel furnish general compliance training that addresses the requirements of the provider's CIA and introduces employees to the provider's overall compliance program.
- The IRO performs routine tasks relating to the provider's confidential disclosure program, such as answering the confidential hotline or transcribing the allegations received via the hotline.
- The IRO performs the ineligible persons screening by entering the employee names into the exclusion databases and providing the screening results back to the provider.
- The IRO evaluates the provider's existing compliance program before the provider's CIA is executed, presents its conclusions regarding the strengths and weaknesses of the provider's existing compliance program, and makes recommendations regarding areas for improvement.
- The IRO provides personnel to perform work plan procedures that are developed by the provider's internal audit department and are not related to the subject matter of the CIA reviews.
- The IRO furnishes consulting services to the provider under an engagement that is completed prior to the start of the CIA reviews and the services (1) are not related to the subject matter of the CIA reviews and (2) do not involve the performance of management functions.
- The IRO performs an assessment of the strengths and weaknesses of the provider's internal controls, even if those controls relate to the subject matter of the CIA review, as long as the IRO is not responsible for designing or implementing

[10] Government Auditing Standards, paragraph 3.22.
[11] Government Auditing Standards, paragraph 3.25.

corrective action based on its internal controls assessment, or otherwise performing management functions.

Services That Likely Would Impair the IRO's Independence and Objectivity:

- A provider uses a billing system or coding software that was developed or designed by the IRO and the IRO is being engaged to perform a claims review (the system or software would be significant or material to the subject matter of the review).
- IRO personnel furnish specific training that addresses the subject matter of the CIA review (the specific training would be significant or material to the subject matter of the review).
- The IRO develops the provider's policies, procedures or internal control systems (this is making management decisions and may also be significant or material to the CIA review if the policies and procedures address the risk areas that are the subject of the review).
- The IRO participates in decision making relating to the confidential disclosure program, such as determining which allegations warrant further investigation or the appropriate corrective action to take in response to compliance allegations (this would be making management decisions).
- The IRO performs an assessment of the strength and weaknesses of the provider's internal controls associated with the specific risk areas that are addressed in the CIA and is engaged by the provider to design or implement new processes or internal controls that relate to the subject matter of the CIA reviews (the IRO would be involved in making management decisions or performing management functions).
- The provider outsources its internal audit function to the IRO (this would involve the IRO performing management functions).
- The IRO is engaged to provide consulting services to the provider during the term of the CIA on a matter that is related to the subject matter of the CIA reviews (these services would be significant or material to the subject matter of the CIA review).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

March 13, 2012

VIA ELECTRONIC MAIL

Sheila Sawyer, Esq.
General Counsel and Chief Administrative Officer
Church Street Health Management
618 Church Street
Suite 520
Nashville, TN 37219

Lorri Steiner
Chief Compliance Officer
Church Street Health Management
618 Church Street
Suite 520
Nashville, TN 37219

RE: Notice of Material Breach and Intent to Exclude

Dear Ms. Sawyer and Ms. Steiner:

The purpose of this letter is to formalize the terms of an agreement between Church Street Health Management, formerly known as FORBA Holdings, LLC (hereinafter, "CSHM") and the Office of Inspector General (OIG) of the United States Department of Health and Human Services. This letter agreement specifies the general terms discussed by the OIG during our meeting on March 13, 2012.

As you are aware, the purpose of this meeting was to discuss CSHM's March 12, 2012 response to the OIG's Notice of Material Breach and Intent to Exclude (Notice) which was issued to CSHM on March 8, 2012 pursuant to the OIG's rights and authorities under the Corporate Integrity Agreement (CIA) executed between CSHM and the OIG. As we discussed during our meeting this morning, the OIG has determined that: (1) CSHM has cured certain breaches identified in the OIG's Notice; (2) the OIG is satisfied with CSHM's response to certain breaches that may not necessarily be cured at this time; and (3) CSHM has failed to satisfy the OIG that certain breaches identified in the OIG's Notice can or will be cured by CSHM within the requisite timeframe under the CIA. The OIG agrees not to proceed with an exclusion action for the specific breaches of the CIA identified in our Notice in exchange for CSHM's agreement to: (1) a voluntary exclusion of Small Smiles Dental Center of Manassas (Manassas Center) if CSHM fails to divest, transfer, and/or sell Manassas Center within 90 days; and (2) assume additional integrity-related obligations incorporated as an amendment to the CIA by this letter.

OIG's Determination that Certain Breaches are Cured

In our Notice, the OIG determined that CSHM was in material breach of its CIA for its failure to comply with the obligations of Sections III.I.2.c and III.I.2.d of the CIA. In its response to the Notice, CSHM has advised the OIG of its effort to cure this specific breach through its provision of written notice to the Virginia state licensing board of CSHM's investigation of issues at the Manassas Center. The OIG considers CSHM's response to have cured its breach of Sections III.I.2.c and III.I.2.d of the CIA.

In our Notice, the OIG determined that CSHM was in material breach of its CIA for CSHM's failure to comply with Section III.B.2.u of the CIA. In its response to the Notice, CSHM has advised the OIG of its effort to cure this specific breach through: (1) the revision of CSHM's policy entitled "Adverse Events, Quality of Care Reportable Events, and OMIG Patient Care Matters," and (2) CSHM's termination of the Covered Person identified in CSHM's September 26, 2011 Quality of Care Reportable Event Notice to the OIG. The OIG considers CSHM's actions described in its response to have cured its breach of Section III.B.2.u of the CIA.

OIG's Determination that CSHM's Response is Satisfactory with Respect to Breaches that Could not be Cured

In our Notice, the OIG determined that CSHM was in material breach of its CIA for CSHM's submission of a false certification under Section III.A.7 of the CIA. In its response to the Notice, CSHM indicated that it could not cure the breach of having submitted a false certification, but that the Certifying Employee who signed the false certification is no longer employed by CSHM. CSHM also indicated in its response to the Notice that it has "implemented significant training and revamped our process for

certifications" under the CIA and described many such actions. The OIG considers CSHM's actions described in its response to be satisfactory with respect to the breach as cited under Section III.A.7 of the CIA.

OIG's Determination that Certain Breaches have not been Cured or Cannot be Cured within the Requisite Timeframe

In our Notice, the OIG determined that CSHM was in material breach of its CIA for CSHM's failure to comply with Sections III.B.2.d, III.B.2.g, and III.B.2.n of the CIA. The OIG has reviewed CSHM's March 12, 2012 response and determined that CSHM has failed to demonstrate to the OIG's satisfaction that the breaches under Sections III.B.2.d, III.B.2.g, and III.B.2.n of the CIA have been or will be cured within the requisite timeframe required by Section X.E.3 of CIA.

As we indicated in our meeting this morning, the OIG agrees not to pursue an exclusion action for CSHM's breach of Sections III.B.2.d, III.B.2.g, and III.B.2.n of the CIA, as specifically addressed in our Notice, in exchange for CSHM's agreement to: (1) a voluntary exclusion of Manassas Center within 90 days of the date of this letter; and (2) comply with additional integrity-related obligations that will be incorporated as an amendment to the CIA by this letter.

We understand that CSHM is in the process of closing or transferring the Manassas Center to an unrelated third party. In the event CSHM transfers the Manassas Center to an unrelated third party within 90 days of the date of this letter and CSHM has no affiliation or relationship with the new owner, the OIG would not pursue an exclusion of Manassas Center. In the event CSHM does not close or transfer The Manassas Center as described above, CSHM agrees that the Manassas Center shall be excluded from participation in the Federal health care programs.

The additional integrity-related obligations that the OIG will require are detailed as follows:

1. Compliance Program Onsite Reviews of CSHM Facilities. Within 30 days, CSHM shall develop and implement a process by which the Chief Dental Officer, the Compliance Officer, and Regional Dentists shall conduct at least one onsite review ("Onsite Review") each month to a CSHM facility for the purpose of evaluating and ensuring compliance with all applicable Federal health care program requirements, state dental board requirements, and the obligations of the CIA. The OIG will require CSHM to recruit Regional Dentists who will assist with the Onsite Reviews as well as assisting the Chief Dental Officer with the review of patient care matters at CSHM and CSHM facilities, including but not limited to quality protocols, quality assessments, patient safety issues, utilization

review, performance improvement, and dental staff training. Regional Dentists will be required to maintain board-certification in pediatric dentistry and have experience treating pediatric Federal health care program beneficiaries. Within 30 days, CSHM shall prepare and submit to the OIG a plan to recruit Regional Dentists. The selection of CSHM facilities that will be subject to the Onsite Review should be based upon CSHM's evaluation of chart audit results, quality assurance indicators, CRAFT reports and complaints. Each Onsite Review shall include, at a minimum, the direct observation of patient care by the Chief Dental Officer and Regional Dentists, and an in-person review of CIA obligations by the Compliance Officer with the Lead Dentist and Compliance Liaison. Within 30 days after conducting an Onsite Review, the Chief Dental Officer and Compliance Officer shall prepare a written report of the onsite review ("Onsite Review Report") which shall provide details of the Onsite Review, and any findings, observations, and/or corrective action developed as a result of the Onsite Review. CSHM shall provide copies of all Onsite Review Reports to the OIG and the Independent Monitor.

2. Quality Improvement Initiatives. Within 30 days, CSHM shall develop and implement a process by which CSHM identifies specific risk areas and relevant quality benchmarks, taking into account the recommendations of the Independent Monitor, for the purpose of measuring and achieving quality improvement goals on an ongoing basis ("Quality Improvement Initiative"). The Quality Improvement Initiative shall be in addition to the current quality metrics maintained by CSHM. CSHM shall provide, on an ongoing basis, the identified risk areas and relevant quality benchmarks under the Quality Improvement Initiative to the OIG and the Independent Monitor.

3. Referral Process. Within 30 days, CSHM shall develop and implement guidance for each CSHM facility regarding patient referrals from CSHM facilities to other facilities better equipped to treat a patient in specific circumstances involving concerns for patient safety, including but not limited to anesthesia requirements, and behavior guidance techniques. Within 30 days, CSHM shall provide the OIG and the Independent Monitor with a listing of facilities to which referrals may be made for each CSHM facility. If no such referral-receiving facilities exist for any CSHM facility within the 30-day timeframe, CSHM shall provide the OIG and the Independent Monitor with an acceptable plan to identify or develop such facilities for those CSHM facilities.

4. Certifying Employee Certifications. Within 30 days, CSHM shall develop a specific process by which Certifying Employees shall perform a comprehensive assessment of the area under the Certifying Employee's supervision for purposes

of completing the Certifying Employee Certification process under Section III.A.7 of the CIA. The purpose of this requirement is to engage Certifying Employees in the process of evaluating and ensuring compliance with all applicable Federal health care program requirements, state dental board requirements, and the obligations of the CIA.

5. Pulp-to-Crown Medical Necessity Review. Within 120 days, CSHM will perform a review of claims documentation associated with CSHM dentists with high "pulp-to-crown" ratios to determine whether such documentation supports the medical necessity of the services ("Pulp-to-Crown Medical Necessity Review"). CSHM will adopt the appropriate ratio as determined by the Independent Monitor in order to identify all dentists who may be at risk for high "pulp-to-crown" utilization ("Reviewed Dentists"). CSHM will then perform the Pulp-to-Crown Medical Necessity Review for all claims submitted by or on behalf of the Reviewed Dentists from the Effective Date of the CIA to present. Within 150 days, CSHM shall prepare a Pulp-to-Crown Medical Necessity Review Report and provide copies to the OIG and the Independent Monitor. The Independent Monitor will perform a validation review of CSHM's Pulp-to-Crown Medical Necessity Review. CSHM shall report to the OIG all overpayments determined by the Pulp-to-Crown Medical Necessity Review; further, CSHM agrees to refund within 30 days all overpayments determined by the Pulp-to-Crown Medical Necessity Review to the appropriate payors. CSHM will also be required to comply with all relevant provisions of the CIA as a result of findings under the Pulp-to-Crown Medical Necessity Review.

As we discussed, the OIG will instruct the Independent Monitor to carefully evaluate the extent to which CSHM has complied with its obligations under the CIA and, in particular, the additional CIA obligations that we outline in this letter.

The parties agree that this letter shall serve as an amendment to the CIA and that CSHM's failure to implement the additional integrity obligations set forth in this letter shall be a Material Breach under Section X.E.1 and shall be subject to Stipulated Penalties under Section X.B.1 of the CIA. The parties agree that the OIG has relied upon the representations of CSHM in its March 12, 2012 letter. In the event that the OIG determines CSHM's representations were not accurate, the OIG may reinstate its Notice and pursue an exclusion of CSHM.

If CSHM agrees to the terms of this letter, please provide the countersignatures below and return this letter no later than Wednesday, March 14, 2012. If you have any questions regarding this letter or CSHM's obligations under its CIA, please contact Felicia Heimer at (305) 536-6927.

Sincerely,

/Robert K. DeConti/ Acting for
Gregory E. Demske
Assistant Inspector General for Legal Affairs

/Sheila W. Sawyer/ 3/14/2012
Sheila Sawyer, Esq. Date
General Counsel, Chief Administrative Officer
Church Street Health Management

/Lorri L. Steiner/ 3/14/2012
Lorri Steiner Date
Senior Vice President, Chief Compliance Officer
Church Street Health Management

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 447

Medicaid Program; Covered Outpatient Drugs; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2345–P]

RIN 0938–AQ41

Medicaid Program; Covered Outpatient Drugs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise requirements pertaining to Medicaid reimbursement for covered outpatient drugs to implement provisions of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act). This proposed rule would also revise other requirements related to covered outpatient drugs, including key aspects of Medicaid coverage, payment, and the drug rebate program. Therefore, we are proposing to amend 42 CFR part 447, subpart I to implement specific provisions of the Affordable Care Act.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 2, 2012.

ADDRESSES: In commenting, please refer to file code CMS–2345–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2345–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2345–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters must leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed. The comments delivered must also be stamped in to verify timeliness of submission.)

b. For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and if received after the comment period closes may not be considered.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Angel Davis, (410) 786–4693, and Meagan Khau, (410) 786–1357, for issues related to rebates for line extensions.

Lisa Ferrandi, (410) 786–5445, for issues related to the Collection of Information Requirements.

Joseph Fine, (410) 786–2128, for issues related to the determination of Best Price, definition of covered outpatient drug and rebates for drugs dispensed by Medicaid managed care organizations.

Christine Hinds, (410) 786–4578, Kimberly Howell, (410) 786–6762, Terry Simananda, (410) 786–8144, or Wendy Tuttle, (410) 786–8690, for issues related to the determination of Average Manufacturer Price (AMP).

Meagan Khau, (410) 786–1357, for issues related to the offset of rebates.

Madlyn Kruh, (410) 786–3239, for issues related to authorized generics, nominal price, investigational drugs, and the coverage of tobacco cessation drugs under the Medicaid State Plan.

Bernadette Leeds, (410) 786–9463, for issues related to drug rebates.

Gail Sexton, (410) 786–4583, for issues related to Federal upper limits.

Marge Watchorn, (410) 786–4361, for issues related to the Regulatory Impact Analysis.

Wendy Tuttle, (410) 786–8690, for all other inquiries.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–(800) 743–3951.

I. Background

A. Introduction

Under the Medicaid program, States may provide coverage of outpatient drugs as an optional service under section 1905(a)(12) of the Social Security Act (the Act). Section 1903(a) of the Act provides for Federal financial participation (FFP) in State expenditures for these drugs. In general, in order for payment to be made available under section 1903 for covered outpatient drugs, manufacturers must enter into a Medicaid drug rebate agreement as set forth in section 1927(a)

of the Act. Section 1927 of the Act provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, and requirements for States for covered outpatient drugs.

This proposed rule would implement changes to section 1927 of the Act made by sections 2501, 2503, and 3301(d)(2) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, enacted on March 23, 2010), and sections 1101(c) and 1206 of the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152, enacted on March 30, 2010), (collectively known as the Affordable Care Act). It would also implement changes to section 1927 of the Act as set forth in section 202 of Pub. L. 111–226, enacted on August 10, 2010 (referred to as the Education Jobs and Medicaid Funding Act). This proposed rule would implement other miscellaneous provisions pertaining to covered outpatient drugs. It would implement changes to section 1927 of the Act as set forth in section 221 of Division F, Title II, of the Omnibus Appropriations Act, 2009, (Pub. L. 111–8, enacted on March 11, 2009). It would also codify other requirements in section 1927 of the Act pertaining to the Medicaid drug rebate (MDR) program and revise certain regulatory provisions presently codified at 42 CFR part 447, subpart I and make other changes concerning rebate requirements. As discussed below, these proposed revisions are consistent with the Secretary's authority set forth in section 1102 of the Act to publish regulations that are necessary to the efficient administration of the Medicaid program.

B. Changes Made by the Affordable Care Act

Section 2501(a) of the Affordable Care Act amended section 1927(c) of the Act by increasing the minimum rebate percentage for most single source and innovator multiple source drugs from 15.1 percent of the average manufacturer price (AMP) to 23.1 percent of AMP. Section 2501(a) of the Affordable Care Act also amended section 1927(c) of the Act by establishing a minimum rebate percentage of 17.1 percent of AMP for certain single source and innovator multiple source clotting factors and single source and innovator multiple source drugs approved by the Food and Drug Administration (FDA) exclusively for pediatric indications. Section 2501(a) of the Affordable Care Act also added section 1927(b)(1)(C) to the Act to make changes to the non-Federal share of rebates by specifying that the amounts attributable to the increased rebate percentages be remitted to the Federal government. The amendments made by section 2501(a) of the Affordable Care Act were effective January 1, 2010.

Section 2501(b) of the Affordable Care Act amended section 1927(c) of the Act by increasing the rebate percentage for noninnovator multiple source drugs from 11 percent of AMP to 13 percent of AMP, effective January 1, 2010.

Section 2501(c) of the Affordable Care Act amended section 1903(m) of the Act by specifying new conditions for managed care organization (MCO) contracts, including that covered outpatient drugs dispensed to individuals eligible for medical assistance under Title XIX of the Act who are enrolled with a Medicaid MCO shall be subject to the same rebate required by the rebate agreement authorized under section 1927 of the Act. The Affordable Care Act also amended section 1903(m) of the Act to establish that MCO capitation rates shall be based on actual cost experience related to rebates and subject to Federal regulations at § 438.6 regarding actuarial soundness of capitation payments. The legislation also provided that MCOs are responsible for reporting to the State certain utilization data and such other data as the Secretary determines necessary for the State to access the rebates authorized by this provision.

Section 2501(c) of the Affordable Care Act also made conforming amendments to section 1927(b) of the Act by requiring manufacturers that participate in the MDR program to provide rebates for drugs dispensed to individuals enrolled with a MCO, if the MCO is responsible for coverage of such drugs. It also amended section 1927(b) of the Act by requiring States to include information on drugs paid for by Medicaid MCOs under the State plan during the rebate period when requesting rebates from manufacturers. Finally, section 2501(c) modified section 1927(j)(1) of the Act to specify that covered outpatient drugs are not subject to the rebate requirements if such drugs are both subject to discounts under section 340B of the Public Health Service Act (PHSA) and dispensed by health maintenance organizations (HMOs), including Medicaid MCOs. The amendments made by section 2501(c) were effective March 23, 2010.

Section 2501(d) of the Affordable Care Act, as revised by section 1206(a) of HCERA, added a new subparagraph (C) to section 1927(c)(2) of the Act, effective for drugs paid for by a State on or after January 1, 2010. This provision modifies the unit rebate amount (URA) calculation for a drug that is a line extension (new formulation) of a single source or innovator multiple source drug that is an oral solid dosage form.

Section 2501(e) of the Affordable Care Act amended section 1927(c)(2) of the Act by adding a new subparagraph (D) and establishing a maximum on the total rebate amount for each single source or innovator multiple source drug at 100 percent of AMP, effective January 1, 2010.

Section 2501(f) of the Affordable Care Act made conforming amendments to section 340B of the Public Health Service Act, which are not addressed in this proposed rule.

Section 2503(a) of the Affordable Care Act amended section 1927(e) of the Act by revising the Federal upper reimbursement limit to be no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. Additionally, it specifies that the Secretary shall implement a smoothing process for AMP which shall be similar to the smoothing process used in determining the average sales price (ASP) of a drug or biological under Medicare Part B. It amended section 1927(k) of the Act by revising the definition of AMP to mean the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.

It also amended the definition of multiple source drug to specify, in part, that a covered outpatient drug qualifies as a multiple source drug if at least one other therapeutically equivalent drug product is sold or marketed in the United States, as opposed to in a State, during the rebate period. It added to section 1927(k) of the Act definitions of retail community pharmacy and wholesaler for purposes of section 1927 of the Act.

Section 2503(b) of the Affordable Care Act amended section 1927(b) of the Act by establishing a requirement that manufacturers report, not later than 30 days after the last day of each month of a rebate period under the agreement, on the manufacturer's total number of units that are used to calculate the monthly AMP for each covered outpatient drug. It also amended the preexisting requirement that the Secretary disclose

AMPs to instead require the Secretary to post, on a Web site accessible to the public, the weighted average of the most recently reported monthly AMPs and the average retail survey price determined for each multiple source drug in accordance with section 1927(f) of the Act.

Section 2503(c) of the Affordable Care Act amended section 1927(f) of the Act by clarifying that the survey of retail prices described in such subsection applies to retail community pharmacies.

Section 2503(d) of the Affordable Care Act specified that the amendments made by section 2503 of the Affordable Care Act were effective October 1, 2010. Section 2503(d) of the Affordable Care Act further specified that the amendments made by section 2503 shall take effect without regard to whether final regulations to carry out such amendments have been issued by October 1, 2010.

Section 3301(d)(2) of the Affordable Care Act included a conforming amendment to the definition of "best price" under Medicaid at section 1927(c)(1)(C) of the Act. This amendment provides that any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A of the Act are exempt from a manufacturer's best price calculation, effective for drugs dispensed on or after July 1, 2010.

Section 7101(a) of the Affordable Care Act expanded the drug discount program under section 340B of the Public Health Service Act (PHSA) to include certain children's hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals.

Section 204 of the Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111–309) revised section 340B of the PHSA by removing children's hospitals from the orphan drug exclusion described in section 2302 of HCERA.

Section 1101(c) of HCERA also includes a conforming amendment to the definition of AMP under Medicaid at section 1927(k) of the Act by providing that discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A of the Act are excluded from a manufacturer's determination of AMP, effective March 30, 2010.

C. Final Rule With Comment Period Published July 17, 2007

On July 17, 2007, CMS published a final rule with comment period in the **Federal Register** (72 FR 39142). The purpose of the final rule with comment period was to finalize the provisions of the proposed rule CMS published in the **Federal Register** on December 22, 2006 (71 FR 77174) and to allow for further public comment on the AMP and Federal upper limit (FUL) outlier sections of the final rule. We received a variety of comments from drug manufacturers, membership organizations, wholesalers, law firms, PBMs, consulting firms and pharmacists in support of, and raising concerns with, the AMP and FUL provisions. However, we note that these regulatory provisions were withdrawn through the final rule published in the November 15, 2010 **Federal Register** (75 FR 69591). Accordingly, we will not be considering the comments received on the July 17, 2007, rule in this rulemaking document. Further, because the Affordable Care Act made substantial changes to the AMP and FUL provisions in section 1927 of the Act, we no longer expect to publish that final rule and we do not expect to address those comments in subsequent rulemaking.

D. Other Changes Concerning the Medicaid Drug Rebate Program

We are also proposing changes to address other program issues related to covered outpatient drugs, including key aspects of Medicaid payment and the MDR program, such as reimbursement to pharmacies for the ingredient cost of a drug, determination of AMP for authorized generic drugs, and the inclusion of territories in the MDR program. These changes are described in greater detail below under section II. Provisions of the Proposed Regulations.

II. Provisions of the Proposed Regulations

This proposed rule would revise regulations concerning the MDR program, set forth at section 1927 of the Act. It implements, consistent with our general rulemaking authority, sections 2501, 2503, and 3301(d)(2) of the Affordable Care Act and sections 1101(c) and 1206 of HCERA, which revise requirements concerning the rebate program and payments for prescription drugs under the Medicaid program. The specific provisions we propose are described in detail below.

A. Basis and Purpose (§ 447.500)

Section 2501(c) of the Affordable Care Act established new requirements for manufacturers that participate in the MDR program to pay rebates for drugs dispensed to individuals enrolled with a Medicaid MCO if the MCO is responsible for coverage of such drugs. We propose to add § 447.500(a)(4) which would specify sections 1903(m)(2)(A)(xiii) and 1927(b) of the Act as the basis for rebates for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled in Medicaid MCOs. We propose to add § 447.500(a)(5) which would add section 1902(a)(30)(A) as an additional basis for calculating payments for covered outpatient drugs.

B. Definitions (§ 447.502)

1. Actual Acquisition Cost

States generally reimburse pharmacies for covered outpatient drugs that are prescribed and dispensed to Medicaid beneficiaries based on a two-part formula, which addresses the ingredient cost of a drug and a reasonable dispensing fee. Each State has the flexibility to determine the amount it will reimburse for each component of the formula based on the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular drug labeler and the cost associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. These reimbursement formulas are subject to review and approval by CMS through the State plan amendment (SPA) process.

In general, States currently reimburse for the covered outpatient drug based, in part, on the estimated acquisition cost (EAC). The EAC, as currently defined in Federal regulations at § 447.502 is the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers. We are proposing to both rename and revise this definition in this proposed rule.

Section 1902(a)(30)(A) of the Act requires, in part, that States have methods and procedures to assure that payment for Medicaid care and services is consistent with efficiency, economy, and quality of care. In accordance with these provisions and in light of the OIG reports concerning published prices (OIG Audit reports—A–06–00–00023, A–06–01–00053, A–06–02–00041),[1] we believe it is necessary for States to have a more accurate reference price to base reimbursement for prescription drugs. Therefore, we propose to replace the term, "estimated acquisition cost" with "actual acquisition cost" (AAC). We believe that changing this definition for

[1] *http://oig.hhs.gov/oas/reports/region6/60000023.htm; http://oig.hhs.gov/oas/reports/region6/60100053.htm; http://oig.hhs.gov/oas/reports/region6/60200041.htm.*

the drug ingredient component of the reimbursement formula to AAC will be more reflective of actual prices paid, as opposed to estimates based on unreliable published compendia pricing. While we recognize that States may not be able to determine the actual price of each individual drug, payment based on an average of the actual acquisition costs from a number of representative pharmacies would still fit within this definition, as data used in the calculation of the average acquisition cost would be reflective of actual purchase prices for pharmacy providers. Within this framework, States can develop payment methodologies consistent with this regulatory definition for their Medicaid pharmacy reimbursement. Therefore, in § 447.502, we propose to define actual acquisition cost as the agency's determination of the actual prices paid by pharmacy providers to acquire drug products marketed or sold by specific manufacturers. This issue and its possible effects on ingredient cost reimbursement is discussed further in both § 447.512 Drugs: Aggregate upper limits of payment and § 447.518 State plan requirements, findings, and assurances.

2. Authorized Generic Drug

The definition of "authorized generic drug", presently set forth in § 447.506(a), applies to rebate calculations, as set forth in subpart I "Payment for Drugs." Therefore, we propose to remove the definition of "Authorized generic drug" from § 447.506 and move this definition to § 447.502. We would continue to define the term "Authorized generics drugs" as any drug sold, licensed or marketed under an NDA approved by the FDA under section 505(c) of the Federal Food Drug and Cosmetic Act (FFDCA) that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the listed brand drug.

For purposes of the MDR Program, an authorized generic is any drug product marketed under the innovator or brand manufacturer's New Drug Application (NDA) approved under section 505(c) of the FFDCA, but labeled with a different NDC than the innovator or brand product. Authorized generics are categorized as innovator multiple source drugs for the purpose of computing the drug rebate.

3. Bona Fide Service Fee

In the July 17, 2007 AMP final rule, we defined bona fide service fees as fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. The Affordable Care Act specifies that the AMP shall exclude bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies including, but not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs). In § 447.502, we propose to revise our current definition of bona fide service fees to include these fees paid by manufacturers to wholesalers or retail community pharmacies.

4. Bundled Sales

In the AMP final rule published on July 17, 2007, bundled sale was defined as an arrangement, regardless of physical packaging, under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drugs sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs in the bundle. In response to manufacturer questions regarding whether a discount and resulting price for each product in a single customer contract that is independent and not contingent on the discount or pricing of any other product in the contract should be applied across all products; we stated previously that where a discount or price concession is established independently and not conditioned upon any other purchase or performance requirement (for example the achievement of market share, inclusion or tier placement on a formulary), or where the discount is not greater than if purchased outside of multi-product arrangement, there is no bundle within the meaning described in § 447.502. Though this is not addressed in the Affordable Care Act, we continue to agree with our response to this issue and thus have decided to include it in this discussion in order to further clarify the bundled sale definition. Therefore, we propose to add the following clarifying statement to the definition of bundled sale: The discounts in a bundled sale, including but not limited to those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs sold under the bundled arrangement.

5. Clotting Factor

The Affordable Care Act established a minimum rebate percentage of 17.1 percent of AMP for a single source drug or an innovator multiple source drug that is a clotting factor for which a separate furnishing payment is authorized under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by the Secretary. Consistent with these provisions, we propose to define clotting factors as those drugs or products for which a separate furnishing payment is authorized under section 1842(o)(5) of the Act and which are included on a list of such factors specified and updated quarterly by CMS.

6. Covered Outpatient Drug

In accordance with section 1927 of the Act, manufacturers that have entered into a Rebate Agreement with the Secretary are responsible for paying rebates to States for their covered outpatient drugs for which payment has been made under the state plan. Manufacturers are responsible for submitting required drug product data, including each drug's NDC. This NDC information is placed on the MDR file and used for assuring compliance with the statutory requirements.

There have been products identified in the drug product data file that do not meet the definition of a covered outpatient drug. Therefore, we believe it is necessary to provide clarification regarding the definition of a covered outpatient drug in section 1927(k)(2) of the Act and the limiting definition at section 1927(k)(3) of the Act. Accordingly, we propose to add a definition of covered outpatient drug to § 447.502.

We propose that a drug is considered a covered outpatient drug when the drug may be dispensed only upon prescription (except as discussed below with respect to certain non-prescription drugs), and it meets the following criteria as described in section 1927(k)(2) of the Act:

- The drug has been approved for safety and effectiveness as a prescription drug by the FDA under section 505 or 507 of the FFDCA where the manufacturer has obtained a NDA or under section 505(j) of the FFDCA where the manufacturer has obtained an Abbreviated New Drug Application (ANDA);
- The drug was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962, or is identical, similar or related (within the meaning of section 310.6(b)(1) of title 21 of the CFR) to such a drug; and has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act;
- The drug is one which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need or is identical, similar, or related to such a drug and for which the Secretary has not issued a notice for an opportunity for a hearing under section 505(e) of the FFDCA on a proposed order of the Secretary to withdraw approval of an application for such drug under the FFDCA because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended or suggested in its labeling;
- The drug is a biologic product, other than a vaccine which—

(1) May only be dispensed upon prescription,

(2) Is licensed under section 351 of the Public Health Service Act, and

(3) Is produced at an establishment licensed under such section to produce such product; or

- The drug is insulin certified under section 506 of the FFDCA.

Consistent with section 1927(k)(3) of the Act, we propose that, except as discussed below, a drug, biological product, or insulin would not be considered a covered outpatient drug when that drug or product is billed as a bundled service with, and provided as part of or incident to and in the same setting as, any of the following services:

- Inpatient Hospital Services;
- Hospice Services;
- Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;
- Physician services;
- Outpatient hospital services;
- Nursing facility and services provided by an intermediate care facility for the mentally retarded;
- Other laboratory and x-ray services; or
- Renal dialysis.

We further propose that the above exemptions to the definition of covered outpatient drug for combined services would not apply if the drug is carved out and billed separately from the service (for example, an infusion drug and x-ray are billed separately, not as a composite radiology service; therefore, the infusion drug is a covered outpatient drug).

Additionally, section 1927(k)(3) of the Act provides that the definition of covered outpatient drug does not include any such drug or product for which a NDC number is not required by the FDA or a drug or biological used for a medical indication which is not a medically accepted indication. We note that for the purposes of the MDR we use an NDC format at either the NDC–9, which includes the labeler code and product code, to identify the product information, or the NDC–11, which includes the labeler code, product code, and the package code, to identify the product's package information. We are aware that FDA has a slightly different NDC format than what is used in the MDR program. (Please see the discussion under the definition of NDC.) For the purpose of the MDR program, we will continue to use the current NDC format of NDC–9, which includes the labeler code and the product code, to identify the product information and NDC–11, which includes the labeler code, product code, and package code, to identify the product's package information. However, if there is change to the current NDC format as a result of FDA action, then we will issue guidance, as necessary, to notify the public as well as to explain its impact on the MDR program.

We are not involved with and do not have oversight for the designation of the NDC. The FDA requires NDCs for drugs that must be listed with the FDA in accordance with Federal Food, Drug, and Cosmetics Act (FFDCA), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85). (21 CFR 207.25(b)(8)). The FDAAA amended section 510(p) of the FFDCA (21 U.S.C 360) to explicitly require that registration and listing information (including the submission of updated information) required under section 510 of the FFDCA, which includes information from both domestic and foreign establishments, be submitted by electronic means, unless the Secretary of Health and Human Services grants a request for waiver of this requirement because use of electronic means is not reasonable for the person requesting the waiver.

Section 1927(k)(3) of the Act provides that a covered outpatient drug does not include any such drug or product for which an NDC number is not required by the FDA. However, in accordance with section 1927(k)(2), and the requirements of section 510 of the FFDCA, we propose that a drug, whether prescription or over-the-counter (OTC), would only be treated as a covered outpatient drug if the drug is both required to have an NDC and is listed electronically with the FDA. We believe this additional standard is needed to ensure compliance with the prescribed drug provisions, FDA approval provisions, and the NDC listing provisions. Furthermore, this proposal is necessary in order for us to assure compliance with the drug rebate submission requirements, for CMS to verify State utilization data and manufacturer product data, and to assure the correct calculation of the offset amounts mandated by the Affordable Care Act. Additionally, this proposal aligns with a proposal submitted as part of the fiscal year (FY) 2012 President's Budget to require drugs to be properly listed electronically with the FDA as a requirement to be covered under Medicaid.

Therefore, if a manufacturer is required to list all of its NDCs electronically with the FDA, this would ensure that all the products in the MDR program meet the definition of section 1927(k)(3) of the Act. In addition, it would permit us to verify State and manufacturer submissions by referencing the FDA's electronic drug listing information.

Manufacturers are required to update their registration and listing information electronically in accordance with FDA's current registration and listing requirements.

Additionally, in order for us to fully implement these provisions, we are requiring that manufacturers submit any relevant approved FDA application numbers. When a product is listed with the FDA, the manufacturer is required to provide to the FDA the NDC and the application number, if any, for the product (21 CFR 207.25(b)). An

application number will help CMS find information on the approval status to market a drug. See *http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm.* The application number assists CMS in obtaining information from FDA as to whether a drug has been approved under a NDA under section 505 of FFDCA or an ANDA under section 505(j) of FFDCA. This information is critical to the definition of a covered outpatient drug under section 1927(k)(2) of the Act. Under the MDR program reporting requirements, drug manufacturers are required to report to CMS a drug category for each NDC. The drug category represents whether an NDC is classified as a brand name drug (single source drug (S) or innovator multiple source drug (I)) or a generic drug (noninnovator multiple source drug (N)). We use these drug category indications to determine the appropriate rebate percentage to calculate the unit rebate amounts, as well as the offset amounts under the Affordable Care Act.

We are also aware that some products that do not have an approved application number may be covered outpatient drugs. For example, we believe that certain products, such as prenatal prescription vitamins, potassium chloride, codeine sulfate, and hydrocortisone acetate may fall into this category. If a product does not have an FDA application number, in order to be considered a covered outpatient drug, the manufacturer must provide evidence demonstrating that its products meet the statutory definition of a covered outpatient drug under section 1927(k)(2) to 1927(k)(4). We will refer to this evidence of demonstration as covered outpatient drug status, or COD status. We are seeking public comments on this requirement, and in particular, comments identifying drugs or classes of drugs that do not have approved applications but should be deemed covered outpatient drugs.

This submission of data would provide critical information needed to calculate and verify the accuracy of such drug information.

Therefore, we propose that manufacturers report to CMS the number of an approved FDA application for a product or otherwise show that the product meets the statutory definition of a covered outpatient drug under sections 1927(k)(2) and (3) of the Act, in order for CMS to calculate the offset amounts and validate product data to ensure the correct rebate calculation for each NDC in the MDR Program. By having a correct approved FDA application number or the COD status, CMS can more accurately determine the unit rebate amounts and product classification, critical to the rebate percentage calculation.

7. Customary Prompt Pay Discounts

In § 447.502, we propose to add a definition of customary prompt pay discount to ensure consistent application of such discounts among manufacturers when calculating AMP. Therefore, we propose to define customary prompt pay discounts as any discount off of the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a timeframe that is consistent with its customary business practices for payment.

8. Innovator Multiple Source Drug

As currently defined in § 447.502, an innovator multiple source drug means a multiple source drug that was originally marketed under an original new drug application (NDA) approved by the FDA, including an authorized generic drug. It also includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a product license approval (PLA), establishment license approval (ELA), or antibiotic drug approval (ADA). In this rule, we propose to add multiple source drugs originally marketed under a BLA as the BLA approval process is a successor to the PLA and ELA and drugs sold under a BLA are explicitly referenced in the definition of single source drug. To ensure that the correct drug category is reported for an innovator multiple source drug, as was discussed in Manufacturer Release #82, we wish to remind manufacturers, as is consistent with current policy, that an innovator multiple source (I) drug should be reported to CMS for a brand name drug that has therapeutic equivalents available. To determine if therapeutic equivalents are available for a brand name drug or not, you can access the FDA's Drugs@FDA at *http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Addlsearch_drug_name* and search by the Application Number. If therapeutic equivalents are available, then you will see the link to "Therapeutic Equivalents" in the "Drugs Details" page. If there are therapeutic equivalents available for the NDA or BLA, then the brand name drug should be reported as an innovator multiple source drug (I) to CMS.

Additionally, over the course of the MDR program, questions have arisen regarding whether an "original NDA" is the same as an NDA and whether the drug category may be different if a drug is approved under an NDA. We are proposing to clarify that, for purposes of the MDR program, an original NDA is equivalent to an NDA filed by the manufacturer for approval under section 505 of the FFDCA for purposes of approval by the FDA for safety and effectiveness. In light of this definition, we are also proposing to use the term "NDA" when addressing such application types for brand name drugs and not use the term "original NDA" when referring to such drugs throughout this proposed rule.

9. Line Extension Drug (New Formulation)

The Affordable Care Act established a separate calculation for the unit rebate amount for a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form. Section 1927(c)(2)(C) of the Act, added by section 2501(d) of the Affordable Care Act, defines line extension to mean a new formulation of a drug, such as an extended release formulation. We propose to define line extension as a single source or innovator multiple source drug that is an oral solid dosage form that has been approved by the FDA, listed in Drugs@FDA *http://www.accessdata.fda.gov/scripts/cder/drugsatfda/application* file, as a change to the initial brand name listed drug in that it represents a new version of the previously approved listed drug, such as a new ester, a new salt or other noncovalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication for an already marketed drug. We propose that regardless of whether the drug is approved under an NDA or a supplemental NDA, if the change to the drug is assigned to one of the above changes, it will be considered a line extension drug.

These modifications to the initial brand name listed drug are often approved under section 505(b)(2) of the FFDCA. A section 505(b)(2) application is a new drug application submitted under section 505(b)(1) and approved under section 505(c) of the FFDCA. A section 505(b)(2) application is one for which one or more of the investigations relied upon by the applicant to show whether a drug is safe and effective were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. Section 505(b)(2), as described in FDA

regulations at 21 CFR 314.54, may be used in certain circumstances to seek approval of a drug product that represents a modification to a listed drug product. Examples of drugs that have been approved under the 505(b)(2) application include drugs with a new formulation, dosing regimen, change in active ingredient (such as a different salt or ester, combination product), and/or new drug indication. These types of drugs are assigned a Chemical Type by the FDA for the new drug application. A section 505(b)(2) application may be granted 3 years of exclusivity, may be eligible for orphan drug exclusivity or pediatric exclusivity. We have included these changes within our definition of line extension drugs. (See G.2. Treatment of New Formulations for further explanation of CMS' proposal.)

10. Manufacturer

For purposes of the MDR Program, we propose to clarify our current definition of manufacturer by revising it to state that a "manufacturer means any entity that holds the NDC for a covered outpatient drug or biological product". This change in terminology is not intended change the scope of the definition.

11. Multiple Source Drug

On November 15, 2010, we published the "Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs" final rule in the **Federal Register** (75 FR 69591). That final rule withdrew the regulatory definition of multiple source drug. As previously noted, section 2503(a)(3) of the Affordable Care Act amended the definition of multiple source drug set forth in section 1927(k)(7) of the Act.

Therefore, in accordance with section 1927(k)(7) of the Act, as revised, we propose to define multiple source drug in § 447.502 as a covered outpatient drug for which there is at least one other drug product which—

(1) Is rated as therapeutically equivalent. For the list of drug products rated as therapeutically equivalent, we will use the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" which is currently available at *http://www.fda.gov/cder/orange/default.htm* or which can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, Rm. 12A–30, Rockville, MD 20857;

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA; and

(3) Is sold or marketed in the United States during the rebate period.

12. National Drug Code

The Drug Listing Act of 1972 requires each registered drug establishment to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (See section 510 of the FFDCA (21 U.S.C. 360)). Drug products are identified and listed with FDA using a unique identifier called the National Drug Code (NDC). Under FDA regulations in 21 CFR part 207, the NDC is identified as a 10-digit, 3-segment number. The first segment, the labeler code, is assigned by the FDA. A labeler is a firm that manufactures the drug, including a repacker or relabeler, or a firm that distributes the drug under its own trade name or label. The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular firm. The third segment, the package code, identifies the trade package size and type. Both the product and package codes are assigned by the firm. The NDC will be in one of the following configurations: 4–4–2, 5–3–2, or 5–4–1.

In this proposed rule, we clarify that even though FDA currently uses a unique 10-digit NDC, for the purposes of the MDR program and this subpart we will continue to use an NDC format with the NDC–9, which includes the labeler code and the product code, to identify the product information and the NDC–11, which includes the labeler code, product code, and package code, to identify the product's package information. Manufacturers may include a leading zero in the product code or the package code segments of the NDC in order to arrive at the 5–4 NDC–9 or 5–4–2 NDC–11 when reporting their product to the MDR program.

13. Noninnovator Multiple Source Drug

As currently defined in § 447.502, a noninnovator multiple source drug means: (1) A multiple source drug that is not an innovator multiple source drug or a single source drug, (2) a multiple source drug that is marketed under an abbreviated NDA (ANDA) or an abbreviated antibiotic drug application, and (3) a drug that entered the market before 1962 that was not originally marketed under an NDA.

In addition to a noninnovator multiple source drug as described, currently, there are other drugs on the market that have not gone through the FDA approval process, including but not limited to certain prescription prenatal vitamins.

Therefore, we propose to amend the definition of a noninnovator multiple source drug to also include these other drugs that have not gone through FDA approval process but otherwise meet the definition of "covered outpatient drug". However, if any of the drug products listed in this amended definition of a noninnovator multiple source drug subsequently receives a new NDA or ANDA approval from the FDA, the manufacturer must change the reporting of the product's drug category to correlate with the new product application type and furnish the appropriate information.

We also propose to amend the definition of noninnovator multiple source drug to clarify that for purposes of Medicaid payment and rebate calculations, the term shall include noninnovator drugs that are not therapeutically equivalent.

14. Oral Solid Dosage Form

CMS proposes to interpret oral solid dosage form in accordance to the FDA regulation at 21 CFR 206.3, which defines solid oral dosage form to mean capsules, tablets, or similar drug products intended for oral use. We also clarify that although FDA regulations at 21 CFR 206.3 uses the term "solid oral dosage form," section 1927(c)(2)(C) specifically used the term "oral solid dosage form" in reference to the treatment of new formulations. Therefore, CMS will treat the term "oral solid dosage form" to mean the same as FDA's "solid oral dosage form."

CMS proposes to further interpret an oral route of administration as any drug that is intended to be taken by mouth. In accordance with these provisions, CMS is providing manufacturers with guidance in order to assist them in determining which drugs should be considered as oral solid dosage forms (please see Table 1). This list will be updated based on any changes to the FDA's definition of solid dosage forms.

TABLE 1—LIST OF ORAL SOLID DOSAGE FORMS

Bar, Chewable	Capsule
Capsule (Immediate/Complete Release) (Hard Or Soft Gelatin, Chewable Or Perle)	Capsule, Coated
Capsule, Coated (Hard Or Soft Gelatin)	Capsule, Coated Pellets
Capsule, Coated, Extended Release	Capsule, Delayed Action (Hard Or Gelatin, Coated, Enteric Coated)
Capsule, Delayed Release Pellets	Capsule, Enteric Coated Pellets
Capsule, Extended Release	Capsule, Film Coated (Hard Gelatin)
Capsule, Film Coated, Extended Release	Capsule, Gelatin Coated
Capsule, Hard Gelatin	Capsule, Liquid Filled
Capsule, Repeat Action	Capsule, Soft Gelatin
Capsule, Soft Gelatin Liquid-Filled	Capsule, Sustained Action (Hard Or Soft Gelatin, Coated, Film Coated)
Dispersible Tablet	Granule, Enteric Coated
Granule, Delayed Release	Lollipop
Gum (Chewing, Medicated)	Pellet, Coated, Extended Release
Lozenge	Tablet (Immediate/Complete Release) (Coated, Film Coated, Sugar Coated, Multilayer, Uncoated, Buccal, Chewable)
Tablet	Tablet, Coated
Tablet, Chewable	Tablet, Controlled Release
Tablet, Coated Particles	Tablet, Delayed Release
Tablet, Delayed Action (Coated, Enteric Coated)	Tablet, Dispersible
Tablet, Delayed Release Particles	Tablet, Extended Release
Tablet, Enteric Coated Particles	Tablet, Film Coated, Extended Release
Tablet, Film Coated	Tablet, Multilayer, Extended Release
Tablet, Multilayer (Coated, Film Coated)	Tablet, Orally Disintegrating
Tablet, Orally Disintegrating, Delayed Release	Tablet, Soluble
Tablet, Repeat Action (Coated)	Tablet, Sustained Action (Coated, Film Coated, Multilayer, Uncoated)
Tablet, Sugar Coated	Tablet, Uncoated, Lozenge
Tablet, Sustained Release, Film Coated	Tablet, Uncoated, Troche
Tablet, Uncoated, Lozenge, Lypophilized	Pastille
Tablet, Sustained Action, Membrane Controlled	Wafer
Troche/Lozenge	

CMS would not consider the following as oral solid dosage forms because these dosage forms are intended to be made into a liquid or suspension prior to oral consumption.

TABLE 2—LIST OF OTHER DOSAGE FORMS

Capsule, for Micro-emulsion	Granule, Effervescent, for Solution
Granule Effervescent	Tablet, Effervescent
Granule, Effervescent, for Solution	Tablet, for Solution
Granule Effervescent, for Suspension	Tablet Effervescent for Solution
Granule, for Oral Suspension	Tablet, for Suspension

15. Over-the-Counter (OTC) Drug

With the exception of certain tobacco cessation drugs for pregnant women, or an EPSDT service, section 1927(d)(2) of the Act currently allows States to exclude from coverage or otherwise restrict coverage of OTC drugs. We propose to add a definition of OTC drugs in order to clarify which products would be treated as OTC drugs in the Medicaid program. This definition is consistent with our current policy and would not change how these drugs are treated for purposes of coverage under the Medicaid program. We propose to define OTC drugs as drugs that are appropriate for use without the supervision of a health care professional such as a physician, and which can be purchased by a consumer without a prescription, although for Medicaid coverage a prescription continues to be required. OTC drugs may be marketed under an approved premarket application (NDA or ANDA) or in many cases, may be marketed under an OTC monograph. In some instances, FDA permits these drugs to be marketed under a monograph that is not yet final (such as where there is an OTC tentative final monograph), as stated in 21 CFR part 330 and FDA guidance. Unlike NDAs which are based on premarket approval of specific, finished drug products, monographs specify the active ingredients, indications, dosages, and claims that can be made by the OTC drug products.

16. Pediatric Indications

The Affordable Care Act established a minimum rebate percentage of 17.1 percent of AMP for single source and innovator multiple source drugs approved by the FDA exclusively for pediatric indications. To implement this requirement, we propose to clarify which drugs will be subject to this minimum rebate percentage. In regulations at 21 CFR 201.57 and 21 CFR 201.80, the FDA defines pediatric use for most drug labeling to mean use for pediatric populations and pediatric patients, that is, "the pediatric age group, from birth to 16 years, including age groups often called neo-nates, infants, children, and adolescents." Accordingly, given the statutory amendments, we propose to define "a drug approved by the Food and Drug Administration exclusively for pediatric indications" to mean a drug product approved by the FDA exclusively with indications for pediatric use, with the pediatric age group defined from birth to 16 years. Drugs that are not approved and labeled exclusively for pediatric use, that merely reference use in children in any part of the labeling, or that receive a supplemental indication for pediatric use, will not qualify for the minimum rebate of 17.1 percent of AMP as specified in section 1927(c)(1)(B)(iii) of the Act. In accordance with the statute, we propose to apply this definition only to drug products whose FDA-approved labeling includes only indications for children from birth to 16 years of age. Drugs without this explicit age labeling will not satisfy the requirement that the drug be approved exclusively for pediatric use and will not qualify for the minimum rebate of 17.1 percent of AMP. We are proposing to apply such a definition only when this specific pediatric age cohort

appears in the "Indication and Usage" section of the FDA-approved labeling.

17. Professional Dispensing Fee

The definition of dispensing fee will remain unchanged as it already enumerates those costs to dispense a drug that the pharmacy incurs. However, we propose to replace the term "dispensing fee" with "professional dispensing fee" as drug ingredient cost is only one component of the two-part formula that States generally use to reimburse pharmacies for prescribed drugs dispensed to Medicaid beneficiaries; and, we feel that this change from "dispensing fee" to "professional dispensing fee" reinforces our position that once the reimbursement for the drug is properly determined, the dispensing fee should reflect the pharmacist's professional services and costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Therefore, as States change their payment for ingredient cost, we also propose to require States to reconsider the dispensing fee methodology consistent with the revised requirements.

18. Single Source Drug

As currently defined in § 447.502, a single source drug means a covered outpatient drug that is produced or distributed under an NDA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a BLA, PLA, ELA, or ADA.

As previously stated in the discussion of the proposed changes to the definition of innovator multiple source drug, for purposes of the MDR program, we have defined an original NDA as an NDA filed by the manufacturer with the FDA for purposes of approval for safety and effectiveness. Further, we wish to remind a manufacturer that as long as it has an approved NDA number issued by the FDA, a drug is considered to be a single source drug and is required to be reported with as an "S" drug category to CMS under the MDR program unless there are FDA approved therapeutic equivalents. To determine if therapeutic equivalents are available, you can access the FDA's Drugs@FDA and search by the Application Number. If therapeutic equivalents are available for the NDA, then you will see the link to "Therapeutic Equivalents" in the "Drugs Details" page. If there are no therapeutic equivalents available for the NDA, then the brand name drug should be reported as an "S" to CMS.

19. States

Currently, for purposes of this subpart, the term "States" is defined as the 50 States and the District of Columbia. However, excluding the territories from this definition of States prevents them from receiving manufacturer rebates through the MDR program. We recognize that the territories have, over the years, expressed an interest in participating in the MDR program and that such rebates would in part offset the costs of providing Medicaid drugs. We have decided, in accordance with section 1101(a)(1) of the Act, to propose revising the definition of States to include the 50 States, the District of Columbia, and the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa). Therefore, for drug rebates, we believe it is in the best interests of the Medicaid program to include the territories in the definition of States so that they may achieve the savings that drug rebates provide and we propose that the definition of States should be revised accordingly. We also acknowledge that there may be concerns with the territories participating in the MDR program; therefore, we request comments regarding the inclusion of the territories in the definition of States.

20. United States

Similar to our review of the term "States", we also examined our use of the term "United States". As with the term "States," we defined United States only to mean the 50 States and the District of Columbia. However, section 1101(a)(2) of the Act provides that when used in a geographic sense, the term "United States" means, except where otherwise provided, the States. In accordance with this definition, we think it is reasonable to conclude that in this context, the term is used in the geographical sense in that it contemplates the sales of drugs in any of the States. (Please see section II.K. Upper limits for multiple source drugs (§ 447.514) of the preamble for further discussion on the sale of drugs on a nationwide basis.) Therefore, for the purposes of this subpart, we propose, in accordance with section 1101(a) of the Act, to define the "United States" to mean the 50 States plus the District of Columbia and the territories as described above.

21. Wholesaler

The Affordable Care Act added a definition of the term "wholesaler" at section 1927(k)(11) of the Act. We propose to adopt that definition and define wholesaler to mean a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

We are not proposing that a wholesaler be licensed by the State inasmuch as that is not a requirement of the Act, in comparison to the definition of retail community pharmacy, where State licensing is required. In considering how to clarify this term, we reviewed the definition of "wholesale distributor," that appears in section 510(g) of the FFDCA, and regulations at 21 CFR 807.3(s), which provide that the term "wholesale distributor" means "any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user." While this definition is helpful, it does not provide additional clarity to the definition in the Act. Therefore, we are proposing to define wholesaler as set forth in the Act, but are specifically seeking comment on further data sources or definitions we could apply here that would help to further clarify the term wholesaler.

C. Determination of Average Manufacturer Price (§ 447.504)

1. AMP Historical Background

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508) added section 1927 to the Act, which became effective on January 1, 1991. OBRA '90 established the MDR program and defined the AMP with respect to a covered outpatient drug of a manufacturer for a rebate period as the average unit price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. Manufacturers who entered into and had in effect a rebate agreement with CMS were required to report AMP on a quarterly basis. The AMP was used to calculate the rebates paid by manufacturers to the States for drugs

dispensed to their Medicaid beneficiaries.

The Deficit Reduction Act of 2005 (DRA) made significant changes to the Medicaid prescription drug provisions of the Act. The DRA amended section 1927(k)(1) of the Act to revise the definition of AMP to exclude customary prompt pay discounts to wholesalers, effective January 1, 2007. The DRA defined AMP, in part, to mean, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.

Section 6001(c)(3) of the DRA required the Office of Inspector General (OIG) to review the requirements for and manner in which AMP was to be determined and recommend changes to the Secretary by June 1, 2006. Section 6001(c)(3) of the DRA also required the Secretary to clarify the requirements for and the manner in which AMPs are determined by promulgating a regulation no later than July 1, 2007, taking into consideration the OIG's recommendation.

In May 2006, the OIG issued a report, "Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005". In this report the OIG recommended that CMS:

- Clarify the requirements in regards to the definition of retail pharmacy class of trade and treatment of pharmacy benefit manager (PBM) rebates and Medicaid sales; and
- Consider addressing issues raised by industry groups, such as:
  + Administrative and service fees,
  + Lagged price concessions for returned goods,
  + The frequency of AMP reporting,
  + AMP restatements, and
  + Base date AMP.

The OIG also recommended that the Secretary direct CMS to:

- Issue guidance in the near future that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA; and
- Encourage States to analyze the relationship between AMP and pharmacy acquisition cost to ensure that the Medicaid Program appropriately reimburses pharmacies for estimated acquisition costs.

At that time, we recognized that there had been concerns expressed by the OIG and GAO in several prior reports regarding AMP because of inconsistencies in the way manufacturers determine AMP, changes in the marketplace, and the introduction of newer business practices such as payment of services fees. We also realized that, in light of the DRA amendments, AMP would serve two distinct purposes: determining rebates, and serving as the basis for establishing the FUL for multiple source drugs. As a result of a preliminary injunction that had been entered in a lawsuit challenging the definition of AMP, CMS had never used the AMP final rule as a basis for calculating FULs.

Following the enactment of the Affordable Care Act, in the November 15, 2010 **Federal Register** (75 FR 69591), "Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs", we withdrew § 447.504 "Determination of AMP" from the AMP final rule following a period of notice and comment on the proposed withdrawal.

2. AMP Under the Affordable Care Act

On March 23, 2010, the Affordable Care Act was enacted. As noted above, section 2503 of the Affordable Care Act revised the definition of AMP. The Affordable Care Act was further amended by section 202 of the Education Jobs and Medicaid Funding Act (Pub. L. 111–226), which was enacted on August 10, 2010.

For the determination of AMP, the Affordable Care Act revises the definition in section 1927(k) of the Act to eliminate the term "retail pharmacy class of trade" and adds a definition of the term "retail community pharmacy", as well as wholesaler. It identifies specific entities drug manufacturers are to include and exclude from the determination of AMP and (as amended by Pub. L. 111–226) clarifies exceptions to the excluded entities for inhalation, infusion, instilled, implanted, or injectable drugs that are not generally dispensed through a retail community pharmacy.

In this proposed rule, we propose a new § 447.504 "Determination of AMP," which would be based on section 1927(k)(1) of the Act as amended by the Affordable Care Act. Below we provide a detailed discussion of the proposed definition of retail community pharmacy, other terms used in the determination of AMP, the entities proposed for inclusion and exclusion from AMP, and our proposed policy regarding the treatment of inhalation, infusion, instilled, implanted, or injectable drugs (also referred to as 5i drugs, defined in proposed § 447.507), that are not generally dispensed through a retail community pharmacy in the determination of AMP.

These provisions of the Affordable Care Act became effective on October 1, 2010 without regard to whether final regulations to carry out the provisions have been promulgated. Section 2503(a)(2) of the Affordable Care Act revised the definition of AMP to mean, for a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies, and by retail community pharmacies that purchase drugs directly from the manufacturer.

In accordance with section 1927(k)(1)(B)(i) of the Act, as amended by section 2503(a)(2)(B) of the Affordable Care Act, drug manufacturers are to exclude the following from the determination of the AMP:

- Customary prompt pay discounts extended to wholesalers;
- Bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);
- Reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;
- Payments received from, and rebates or discounts provided to, PBMs, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or retail community pharmacy, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy.
- Discounts provided by manufacturers under the Medicare Coverage Gap Discount Program (section 1860D–14A of the Act).

Section 1927(k)(1)(B)(ii) of the Act specifies that, notwithstanding section 1927(k)(1)(B)(i) of the Act, manufacturers are to include in the determination of AMP for a covered outpatient drug any other discounts, rebates, payments, or other financial transactions that are received by, paid

by, or passed through to retail community pharmacies.

How AMP is defined and what sales are included in the determination of AMP affects manufacturers, pharmacy groups, the Federal and State governments and Medicaid beneficiaries, and often there are competing interests at play. The provisions of the Affordable Care Act regarding AMP serve two distinct purposes: Determining rebates and determining the basis for the FUL for multiple source drugs.

There is a direct relationship between which entities are to be included and excluded from AMP calculations and the basis for determining the FUL for multiple source drugs. The Affordable Care Act defines AMP to include prices paid to manufacturers by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer. These sales are typically at higher prices than those of the specifically excluded entities such as the pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, and manufacturers. AMP calculations based on those sales to retail community pharmacies, as opposed to other pharmacies (such as mail order pharmacies), would likely result in a higher AMP value, given that AMP would be limited to higher priced sales. This higher AMP value would benefit the retail pharmacy industry because it is likely that the FUL, based on those AMPs, would be higher and in turn the maximum pharmacy reimbursement, based on those FULs, would be higher. On the other hand, a higher AMP would, in all likelihood, result in higher rebate payments from manufacturers. A broader definition of AMP, which would include sales to entities that purchase drugs at lower prices, would likely lower the AMP value, which in turn would lower drug manufacturer rebate liabilities.

AMP values also have an impact on States and potentially beneficiaries. Increasing AMP values and associated rebate payments would have a direct impact on State expenditures. However, increasing the FULs would also have a direct impact on State payments. On the other hand, if pharmacy reimbursement rates are too low, then it is conceivable that some pharmacies may elect not to participate in the Medicaid program, which could impact beneficiary access to pharmacy services. Similarly, States and the Federal government have an interest in assuring an appropriate level of rebates and beneficiaries' access to care.

3. Definitions

Following is a detailed discussion of the specific terms associated with AMP calculations that we propose to define at § 447.504(a).

a. Average Unit Price

We propose to define average unit price to mean a manufacturer's quarterly sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter. The quarterly sales figure used in this definition represent sales of the drug unit in the lowest identifiable amount (for example, tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams) as reported by the manufacturer.

b. Charitable and Not-for-Profit Pharmacies

For the purposes of this subpart, we propose to define charitable and not-for-profit pharmacies as organizations described in section 501(c)(3) of the Internal Revenue Code of 1986.

c. Insurers

The DRA amended section 1902(a)(25) of the Act by modifying the definition of "third parties" and "health insurers" to clarify the inclusion of self-insured plans, managed care organizations, PBMs, or other parties that are by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service. Although, the DRA clarified "third parties", the Affordable Care Act referenced the term "insurer" in section 1927(k)(1)(B)(IV) of the Act and provided that payments received from many of these third party organizations (for example, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers) be excluded from the AMP calculation.

For the purposes of this subpart, we propose to define insurers as entities that are responsible for the payment of drugs but do not directly purchase drugs from manufacturers and are not in the supply chain to receive delivery of these drugs. Instead, insurers are responsible for payment to pharmacies for drugs dispensed to their members, and do not take actual possession of these drugs.

d. Net Sales

We propose to define net sales to mean quarterly gross sales revenue to wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from manufacturers less cash discounts allowed, and other price reductions (other than rebates under section 1927 of the Act or price reductions specifically excluded by section 1927 of the Act, or regulations under this subpart) which reduce the amount received by the manufacturer.

e. Retail Community Pharmacy

The Affordable Care Act eliminated the term "retail pharmacy class of trade" from the definition of AMP, and added section 1927(k)(10) of the Act to include a definition of the term "retail community pharmacy." This change significantly narrows the entities previously included in the definition of retail pharmacy class of trade. In accordance with the Act, we propose to define retail community pharmacy to mean an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. We further propose to incorporate the requirement set forth in section 1927(k)(10) of the Act that such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

Section 1927(k)(1) of the Act as amended by the Affordable Care Act specifies that manufacturers are responsible for reporting the AMP based upon their sales to retail community pharmacies or wholesalers for drugs dispensed to retail community pharmacies.

In addition, the statutory provision for the determination of AMP suggests there are entities (for example, specialty pharmacies, home infusion pharmacies, and home health care providers), which are conducting business as wholesalers or retail community pharmacies which could be included in the determination of AMP. Section 1927(k)(1)(B)(i)(IV) of the Act excludes from the determination of AMP "payments received from and rebates or discounts provided to * * * any other entity that does not conduct business as a wholesaler or a retail community pharmacy * * *". We believe that to give the provision some meaning, the statute contemplates the inclusion of payments and discounts from those entities that actually conduct business as a wholesaler or retail community pharmacy. This

interpretation gives meaning to this broad exclusion, and provides for a calculation of AMP consistent with our reading of the statute. If an entity that does not conduct business as a wholesaler or retail community pharmacy is to be excluded from the determination of AMP, we considered whether or not it would be reasonable to conclude that payments received from and rebates or discounts provided to an entity that conducts business as a wholesaler or retail community pharmacy should be included in the determination of AMP. Based upon our understanding of the program, certain covered outpatient drugs may only be dispensed through such entities that are conducting business as wholesalers or retail community pharmacies, such as certain oral covered outpatient drugs approved by the FDA requiring a Risk Evaluation and Mitigation Strategy (REMS), to ensure that the benefits of a drug or biological product outweigh its risks. A list of REMS drugs is publically accessible on the FDA Web site at *http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm.*

Some REMS drugs are required to be dispensed by specially certified pharmacies, resulting in certain manufacturers utilizing a restricted network of certified specialty and home infusion pharmacies, which are not specifically included in the definition of retail community pharmacy at section 1927(k)(10) of the Act. In addition, certain oral covered outpatient drugs are dispensed solely through these specialty and home infusion pharmacies. Therefore, if these entities were to be excluded from AMP calculations, an AMP would not be available for these oral covered outpatient drugs. As a result, manufacturers would not be able to calculate rebates for these products and the statutory provisions requiring rebates for such drugs would, in essence, be rendered meaningless. We do not believe that the law should be read to create such a result. Section 1927(b)(1) of the Act requires that manufacturers must provide rebates for all of their covered outpatient drugs for which payment was made under the State plan. These provisions were not amended by the Affordable Care Act. Therefore, we believe in light of the provisions of section 1927(k)(1)(B)(i) of the Act, there is a basis for allowing sales, rebates, and discounts provided to entities conducting business as wholesalers or retail community pharmacies to be included in the determination of AMP for those drugs for which an AMP could not otherwise be calculated. Such an interpretation continues to give meaning to the rebate responsibilities of manufacturers in section 1927(b) of the Act. Therefore, we propose to include in the determination of AMP payments received from and rebates or discounts provided to an entity that conducts business as a wholesaler or retail community pharmacy, such as specialty and home infusion pharmacies, and home healthcare providers, since these entities dispense medications to segments of the general public at retail prices. We specifically invite comments on this part of the proposed rule.

Manufacturers contend that there is an administrative burden and difficulty in obtaining records assuring that their sales to wholesalers are distributed to retail community pharmacies. We took their concerns into consideration and considered whether or not to propose that the sales which cannot be definitely identified as sales to retail community pharmacies or wholesalers for drugs dispensed to retail community pharmacies would be eligible for inclusion in the sales that manufacturers use for AMP calculations. We received comments during the comment period for the Proposed Rule "Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs" published in the **Federal Register** on September 3, 2010 (75 FR 54073) that raised issues regarding the implementation of the new definition of AMP. As these comments were outside the scope of that proposed rule, these comments were not specifically addressed as part of final rule published on November 15, 2010 (75 FR 69591). However, these comments do provide insight into issues of concern for the various stakeholders, especially in regards to the implementation of the new proposed definition of AMP.

One of the issues raised was whether manufacturers should be allowed to presume that sales of drugs are distributed to retail community pharmacies when those sales of drugs are to wholesalers that do not further differentiate their sales among end purchasers.

Based on information provided from these comments it is our understanding that wholesalers generally resell either to manufacturer-contracted customers (which would generate a chargeback or similar record), or to other purchasers with no contract discount arrangement with the manufacturer. In the case of sales to wholesalers where no chargeback record is generated, manufacturers contend that they have minimal to no verifiable information regarding the final transactions on this category of wholesaler re-sales. Manufacturers have expressed concern that they would not have adequate data regarding the wholesaler's actual purchaser to accurately determine if the drug was ultimately sold to retail community pharmacies. Therefore, we considered proposing a so-called "presumed inclusion" policy, where the manufacturer could (absent documentation to the contrary) presume that sales to wholesalers are for drugs distributed to retail community pharmacies, without data concerning that actual distribution. Based upon the comments we received from manufacturers we believe such a policy would be consistent with the market based on the typical chargeback arrangements that manufacturers have in place for institutional and other non-retail community pharmacy purchasers. The presumed inclusion policy would not require manufacturers to obtain data regarding the actual distribution to retail community pharmacies. Through the presumed inclusion policy, in the absence of chargeback or other verifiable data, manufacturers would be able to presume that the sales of drugs to wholesalers are for drugs that are distributed to retail community pharmacies.

However, we recognize that there could be concerns with respect to whether manufacturers should be permitted to presume, in the absence of adequate documentation to the contrary, that prices paid by wholesalers are for drugs that are actually distributed to retail community pharmacies. Allowing this practice of presumptive inclusion could affect the calculation of the FULs for multiple source drugs because it arguably would permit the inclusion of lower AMPs in that calculation based on sales that may not have been actually distributed to retail community pharmacies. It could be argued that if manufacturers are allowed to presume that all drug sales are distributed to retail community pharmacies, AMP would be lower because it could include sales to entities (for example, mail order pharmacies and hospitals) that are able to buy the drugs at lower prices than retail community pharmacies. On the other hand, it could also be argued that, despite these concerns, there would be no adverse consequences to the FULs if manufacturers could presume sales distribution to retail community pharmacies because the sales that would be captured using the presumptive inclusion policy are those sales that do not generate chargebacks. In comments

we received during the comment period for the Proposed Rule, "Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs" published in the **Federal Register** on September 3, 2010 (75 FR 54073), manufacturers claim that allowing the presumed inclusion policy would not create any adverse consequences concerning pharmacy payments. They believe that these sales would, in all likelihood, have a higher net price than institutional or chargeback-generating sales. Additionally, they contend that the volume of AMP-eligible sales used in calculating the FUL could be increased because the additional sales to wholesalers without chargeback data would be added to the volume calculation for determining the weighted average of monthly AMPs. Therefore, they argue that calculating AMPs utilizing the presumptive inclusion policy could result in higher AMPs than AMPs based on actual data and those higher AMPs would be weighted more heavily in the FULs calculation.

We also considered instances where manufacturers are only including in their calculation of AMP those sales where there is adequate verifiable documentation showing that the drug was actually distributed to a retail community pharmacy, whether directly or through a wholesaler. However, we recognize that in this approach there may be instances where the wholesaler actually re-sells the drug to the retail community pharmacies but the manufacturer does not have documentation regarding that actual sale to the retail community pharmacy. Therefore, in contravention of the statute, those sales would not be included in the AMP calculation since the manufacturer does not have adequate documentation.

While we recognize such concerns, we have decided to propose that manufacturers report the AMP based upon their actual sales to retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies. Although we are not proposing a presumed inclusion policy, we did consider both approaches and recognize that there are obstacles with each. We acknowledge that a reasonable alternate approach would be one of presumed inclusion because the statute provides a more structured definition of what is to be included and excluded from AMP. However, we have concerns that a presumed inclusion policy would lead to the inclusion of sales by a manufacturer to entities not contemplated in the statutory definition. Accordingly, for purposes of this proposed rule, we are proposing that manufacturers must calculate AMP based on sales: (1) To wholesalers for drugs distributed to retail community pharmacies, or (2) to retail community pharmacies. We seek comments regarding this section and request information concerning distribution data, specifically data concerning wholesaler sales to the retail community pharmacies so that we can further consider this policy decision.

4. Sales Included in the Determination of AMP

Following is a discussion of specific sales, discounts, rebates, payments, nominal price sales, and other financial transactions that we propose to include in the determination of AMP at § 447.504(b).

a. Sales to Wholesalers (§ 447.504(b)(1))

The definition of AMP in section 1927(k)(1) of the Act, as amended by the Affordable Care Act, specifies that AMP is to be calculated, in part, based on the prices paid by wholesalers for drugs dispensed through retail community pharmacies. Therefore, we propose that sales to wholesalers for drugs distributed to retail community pharmacies are to be included in the determination of AMP.

b. Sales to Other Manufacturers (§ 447.504(b)(2))

We propose that sales to other manufacturers who act as wholesalers are to be included in the determination of AMP to the extent that such sales are for drugs distributed to retail community pharmacies. This provision should be read in concert with the definition of wholesaler found in section 1927(k)(11) of the Act.

c. Retail Community Pharmacies (§ 447.504(b)(3))

Section 1927(k)(1)(B)(ii) of the Act, as revised by the Affordable Care Act specifies that manufacturers are to include in the determination of AMP, discounts, rebates, payments or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies, as defined earlier in this section. Therefore, we propose to include in the determination of AMP, notwithstanding those price reductions specifically excluded by statute or this regulation, discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies. Again, we are unsure to what extent the manufacturer knows that such transactions occur. However, in accordance with our reading of the statute, the manufacturer must include such discounts where it has evidence or documentation demonstrating that such discounts have been passed through to the pharmacy.

d. Entities Conducting Business as Retail Community Pharmacies or Wholesalers, Including But Not Limited to Specialty Pharmacies, Home Infusion Pharmacies and Home Healthcare Providers (§ 447.504(b)(4))

As discussed earlier, we believe in light of the provisions of section 1927(k)(1)(B)(i) of the Act, there is a basis for allowing sales, rebates, and discounts provided to entities conducting business as wholesalers or retail community pharmacies to be included in the determination of AMP for those drugs for which an AMP could not otherwise be calculated. It is our understanding that certain covered outpatient drugs are dispensed primarily, if not solely, through such entities as specialty pharmacies, home infusion pharmacies, or home healthcare providers. We propose that these pharmacies be considered entities that are conducting business as wholesalers or retail community pharmacies. While not specifically identified in the statutory definition of retail community pharmacy, these pharmacies do conduct business as a retail community pharmacy inasmuch as they dispense medications to the general public at retail prices and are licensed by the State as a pharmacy. While they may be serving a specific part of the general public based on a certain medical condition, the drugs dispensed by these pharmacies are sold in the retail marketplace and are available to any member of the general public who has one of these medical conditions. Therefore, we propose that manufacturers are to include in the determination of AMP the sales of covered outpatient drugs that are dispensed through entities conducting business as wholesalers or retail community pharmacies, which include but are not limited to specialty pharmacies, home infusion pharmacies, and home healthcare providers.

5. Sales Excluded From the Determination of AMP

Following is a discussion of specific sales, discounts, rebates, payments and other payments that we propose to exclude from the determination of AMP at § 447.504(c).

a. Prices to Other Federal Programs Including TRICARE—(§ 447.504(c)(1)–§ 447.504(c)(3))

Manufacturers that participate in the MDR program can also participate in other Federal programs which set the prices and/or discounts for drugs, and these prices are not generally available to retail community pharmacies. We propose that in light of section 1927(k) of the Act, prices to Federal programs should be excluded from AMP. These Federal programs include the Indian Health Service (IHS), the DVA, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense (DoD), the Public Health Service (PHS), a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B (a)(4)(L) of the PHSA), the Federal Supply Schedule (FSS) of the General Services Administration (GSA); or any depot prices (including TRICARE) and single award contract prices, of any agency of the Federal government.

On March 17, 2009, the Department of Defense (DoD) issued a regulation entitled, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals (74 FR 11279). That regulation implements section 703 of the National Defense Authorization Act for fiscal year 2008 (NDAA, Pub. L. 110–181) which states that for any prescription filled on or after the date of enactment of the NDAA, the TRICARE Retail Pharmacy Program will be treated as an element of the DoD for purposes of procurement of drugs by Federal agencies under section 8126 of title 38, United States Code (U.S.C.). In accordance with that provision as well as the revised definition of AMP in section 1927(k)(1) of the Act, we propose that TRICARE Retail Pharmacy Program prices should be treated as prices to DoD and therefore excluded from the calculation of AMP.

b. Sales Outside the 50 States, the District of Columbia and Territories (§ 447.504(c)(4))

The proposed definition of "United States" in § 447.502 would define "United States" to mean the 50 States, the District of Columbia and the territories. We, therefore, propose that sales to entities outside the 50 States, the District of Columbia and the territories are not within the scope of the definition of sales to retail community pharmacy, and that drugs sold to these entities would not be considered eligible sales within the definition of AMP. Therefore, we propose that sales to entities not within the 50 States, the District of Columbia or the territories be excluded from the manufacturers' determination of AMP.

c. Hospitals and Hospital Pharmacy Sales (§ 447.504(c)(5))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that sales to hospitals are excluded from the determination of AMP. Further, the term "retail community pharmacy" excludes hospital pharmacies. Therefore, we propose to clarify that sales to hospitals, including direct and indirect sales where the drug is used in either the inpatient setting or the outpatient pharmacy for outpatient hospital use are excluded from the determination of AMP.

d. Sales to Health Maintenance Organizations (HMOs) (Including Managed Care Organizations (MCOs)) (§ 447.504(c)(6))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that sales to HMOs and MCOs are excluded from the determination of AMP. The Affordable Care Act does not specifically address HMO/MCO operated pharmacies. However, given the broad reference in the statute to HMOs and MCOs, we propose to clarify that sales and associated rebates and discounts to HMO/MCO operated pharmacies are excluded from the determination of AMP.

e. Long-Term Care Facility Pharmacies (§ 447.504(c)(7))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that sales and associated rebates and discounts to long-term care providers are excluded from the determination of AMP. Further, the term retail community pharmacy excludes nursing home pharmacies and long-term care facility pharmacies. Therefore, we propose to clarify that sales and associated rebates and discounts to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, long-term care facilities pharmacies, contract pharmacies for the nursing facility where these sales can be identified, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities, be excluded from the determination of AMP.

f. Mail Order Pharmacies (§ 447.504(c)(8))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that the term retail community pharmacy excludes pharmacies that dispense prescription medications to patients primarily through the mail. We consider these to be mail order pharmacies and as such we propose to clarify that sales to mail order pharmacies are excluded from the determination of AMP.

g. Clinics and Other Outpatient Facilities (§ 447.504(c)(9))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that sales to clinics are excluded from the determination of AMP. In 42 CFR 440.90, clinic services is defined as preventative, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. The term includes the following services furnished to outpatients: (a) Services furnished at the clinic by or under the direction of a physician or dentist, and (b) Services furnished outside the clinic by clinic personnel under the direction of a physician to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.

Although the Affordable Care Act did not specifically address the treatment of outpatient facilities in the determination of AMP, we believe that in accordance with the definition of AMP in section 1927(k)(1) of the Act, as well as the definition of clinic in 42 CFR 440.90, sales to outpatient facilities such as surgical centers, ambulatory care centers, dialysis centers, End-Stage Renal Disease clinics, outpatient hospital clinics and mental health centers should be excluded from the AMP. Therefore, we propose to exclude sales and associated rebates and discounts to clinics and outpatient facilities from the determination of AMP.

h. Government Pharmacies (§ 447.504(c)(10))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that the definition of retail community pharmacy does not include government pharmacies. We propose to define government pharmacies as pharmacies operated or owned by Federal, state, county, and municipal governments. We also propose that sales to government

pharmacies are excluded from the determination of AMP.

i. Sales to Charitable and Not-for-Profit Pharmacies (§ 447.504(c)(11)–§ 447.504(c)(12))

Section 1927(k) of the Act, as revised by the Affordable Care Act specifies that the definition of retail community pharmacy does not include charitable or not-for-profit pharmacies. We propose to define charitable or not-for-profit pharmacies as section 501(c) organizations. Section 501(c) organizations are those described in the Internal Revenue Code and are tax-exempt, nonprofit corporations or associations. We propose that sales to these not-for-profit and charitable pharmacies be excluded from the determination of AMP.

j. Insurers § 447.504(c)(13))

The Affordable Care Act defined AMP by specifying that payments received from, and rebates or discounts provided to insurers are to be excluded from the determination of AMP. Therefore, we propose to exclude from the determination of AMP payments received from, and any rebates, discounts, or payments that are provided directly to insurers and that are not passed on to retail community pharmacies.

However, we note that drugs sold to wholesalers for distribution to retail community pharmacies or drugs sold directly to retail community pharmacies that are subsequently reimbursed by insurers when sold by the pharmacy to beneficiaries are part of the chain of sales from manufacturers to wholesalers or retail community pharmacies. In accordance with our reading of the statute, the sales to wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies would be included in AMP calculations, regardless of how the drug is ultimately reimbursed when provided to the beneficiary.

k. Administrative Fees, Including Bona Fide Service Fees, as Well as the Treatment of Group Purchasing Organizations (GPOs) (§ 447.504(c)(14))

As described earlier, we propose to revise the definition of bona fide service fees in § 447.502 to include fees provided as specific examples of bona fide service fees in the Affordable Care Act. The Affordable Care Act specifies that bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies include, but are not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs).

The current regulations define bona fide service fees, in part, to mean fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service. We continue to be concerned that these fees could be used as a vehicle to provide discounts, as opposed to fees at "fair market value" for bona fide services. Thus, to avoid potential fraud concerns, we are retaining our definition, but we have chosen not to define "fair market value" at this time. Due to the rapidly changing market in which new types of arrangements arise, we believe that manufacturers should appropriately determine fair market value and make reasonable assumptions consistent with adequate documentation that will support their payment for these services at fair market rates sufficient that an outside party can determine the basis for the fair market value determination. This is consistent with the 2007 AMP Final Rule (72 FR 39184) and the ASP reporting rule (71 FR 69667).

In accordance with the statute, we propose that bona fide service fees should be excluded from the calculation of AMP. We further propose that, in light of the statutory definition, administrative fees and other fees which are not specifically excluded by the Affordable Care Act, but which meet the definition of bona fide service fees, should also be excluded from the determination of AMP. We are not proposing to further define the type of fees used as examples in the definition of bona fide service fees because we believe that these terms can be read in concert with the current definition of bona fide service fee. As noted previously, they provide specific examples of what could qualify as a bona fide service fee. We note however that retroactive price adjustments, sometimes also known as price appreciation credits, do not meet the definition of a bona fide service fee as they do not reflect any service or offset of a bona fide service performed on behalf of the manufacturer.

The statute does not specifically exclude GPO fees from the AMP calculation. To the extent that bona fide service fees, including, but not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs) and other fees to GPOs meet the definition of "bona fide service fee," we propose that such fees should be excluded from the determination of AMP and are not considered price concessions. However, as consistent with the definition of bona fide service fee at § 447.502 where these fees are passed on in whole or in part to a wholesaler or retail community pharmacy, the fees would not qualify as bona fide service fees. To the extent this occurs, such fees cannot be considered bona fide service fees and, in accordance with section 1927(k)(1)(B)(ii) of the Act, should be included in AMP.

l. Customary Prompt Pay Discounts (§ 447.504(c)(15))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that customary prompt pay discounts that are extended to wholesalers are to be excluded from the determination of AMP. Therefore, we are proposing that customary prompt pay discounts extended to wholesalers be excluded from the determination of AMP.

m. Returned Goods (§ 447.504(c)(16))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of goods, and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction are excluded from the determination of AMP. We propose to incorporate this definition into this rule, but note that it is applicable only to the extent that payment for these returned goods covers the cost of returns and does not otherwise serve as payment to the pharmacy as a price concession. In addition, we propose to exclude the value of returned goods themselves from the determination of AMP when returned in good faith.

We are not proposing to define the terms recalled, damaged, and expired as we believe they are self-explanatory within the standard industry practice. We likewise are not defining unsalable, but would also base it on standard industry practice to determine under what conditions and/or circumstances drugs would be considered unsalable. We are requesting comments regarding whether we should define these terms or further define how these industry standards should be set. We also request examples of what would qualify as unsalable.

n. Medicare Coverage Gap Discount (§ 447.504(c)(17))

Section 3301 of the Affordable Care Act established the Medicare Coverage Gap Discount Program under sections 1860D–43 and 1860D–14A of the Act. Section 1101(c) of the Affordable Care Act further specified that discounts provided by manufacturers under the Medicare coverage gap discount program will be excluded from AMP. Therefore, we propose that discounts under the Medicare coverage gap discount program should be excluded from AMP.

o. PBM Price Concessions (§ 447.504(c)(18))

Section 1927(k)(1)(B) of the Act, as revised by the Affordable Care Act, revised the definition of AMP by excluding payments received from, and rebates or discounts provided to, pharmacy benefit managers (PBMs) and mail order pharmacies. Therefore, we propose to exclude from the calculation of AMP, payments received from and rebates or discounts provided to PBMs, including their mail order pharmacy's purchases to the extent that no part of the rebates, discounts or payments are received by, paid by, or passed through to retail community pharmacies.

p. Treatment of Medicaid Rebates in AMP (§ 447.504(c)(19))

We propose to exclude rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies from the determination of AMP. We are doing so in light of the definition of section 1927(k)(1) of the Act, because these rebates affect the manufacturer and the State, and there is no direct effect on the sale price of these drugs to retail community pharmacies.

Entities not specifically addressed in the statute.

q. Sales to Hospices (§ 447.504(c)(20))

The Affordable Care Act did not specifically address the treatment of sales to hospices in the determination of AMP. We propose, in light of the revisions in sections 1927(k)(1)(A) and 1927(k)(10) of the Act, to exclude hospice sales from the definition of AMP. Hospice pharmacies are outside the scope of the definition of retail community pharmacy. Further, these pharmacies serve a defined population and do not dispense medications to the general public at retail prices.

r. Sales to Prisons (§ 447.504(c)(21))

We propose that the sales to prisons are outside the scope of the definition of retail community pharmacy; drugs sold to these entities serve a defined population in that facility and are not available to the general public.

s. Direct Sales to Physicians (§ 447.504(c)(22) and § 447.504(d)(1))

Except for the sale of inhalation, infusion, instilled, implanted and injectable drugs (also referred to as the 5i drugs, and which are discussed in detail later in this section) we do not believe, in light of the definition of retail community pharmacy in section 1927(k)(10) of the Act, that physicians meet the definition of a retail community pharmacy. However, in light of the specific revisions to section 1927(k)(1)(B)(i)(IV) by section 202 of the Education Jobs and Medicaid Funding Act (Pub. L. 111–226), we believe that certain sales to physicians should be included in AMP. Since we have defined the 5i drugs as those which are primarily physician-administered, we believe in light of the statutory amendments, the case can be made that the sale (and associated discounts) of these 5i drugs to physicians should be included in the determination of AMP. Therefore, we propose in § 447.504(d)(1) that for 5i drugs, sales (and associated rebates or discounts) to physicians are included in the determination of AMP. However, in the case of non-5i drugs, we propose at § 447.504(c)(26) that direct sales to physicians be excluded from the determination of AMP.

t. Direct Sales to Patients (§ 447.504(c)(23))

We propose that direct sales to patients be excluded from AMP as these sales are outside the scope of the definition of retail community pharmacy in section 1927(k)(10) of the Act.

u. Free Goods (§ 447.504(c)(24))

We propose that where a drug or any other item is given away, but not contingent on any purchase requirement, there is no sale and, therefore, that transaction would be excluded from the determination of AMP.

v. Manufacturer Coupons (§ 447.504(c)(25))

We propose in light of the revised definition of AMP that manufacturer coupons to a consumer redeemed by the manufacturer, agent, or another entity acting on behalf of the manufacturer should be excluded from AMP, but only to the extent that the full value of the coupon is passed on to the consumer and the retail community pharmacy does not receive any discount, rebate or price concessions in connection with the manufacturer coupons.

w. Voucher Programs (§ 447.504(c)(26))

We propose that manufacturer vouchers would be excluded from the determination of AMP because the benefits of such vouchers are passed onto the patient and the retail community pharmacy does not receive any discount, rebate or price concessions in connection with the manufacturer voucher programs. However, to the extent that the retail community pharmacy receives a discount, rebate, or other price concession, in accordance with section 1927(k)(1)(B)(ii) of the Act, it shall be included in AMP.

x. Manufacturer-Sponsored Drug Discount Card Programs (§ 447.504(c)(27))

We propose in light of the revised definition of AMP that prices negotiated under a manufacturer-sponsored drug discount program would be excluded from the determination of AMP, provided the discount is passed on to the patient and the retail community pharmacy does not receive any discount, rebate or price concessions in connection with the manufacturer-sponsored drug discount card program.

y. Manufacturer-Sponsored Patient Refund/Rebate Programs (§ 447.504(c)(28))

The Affordable Care Act did not explicitly address the treatment of prices negotiated under a manufacturer-sponsored patient refund or rebate program. To the extent the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the retail community pharmacy does not realize any discounts or rebates or receive any price concession in connection with the manufacturer-sponsored patient refund/rebate programs, we propose in light of the revised definition of AMP that prices negotiated under a manufacturer sponsored patient refund or rebate program would be excluded from the determination of AMP.

z. Copayment and Patient Assistance Programs (§ 447.504(c)(29))

The Affordable Care Act did not address the treatment of patient assistance programs, including copayment assistance programs. We believe in light of the revised definition of AMP that patient assistance programs, including copayment assistance programs that provide free goods that are not contingent on future purchases to patients would be

excluded from the determination of AMP. Therefore, we propose that such patient assistance programs and copayment assistance programs are excluded from the determination of AMP. However, to the extent that the retail community pharmacy receives a discount, rebate, or other price concession in connection with the copayment and patient assistance programs, in accordance with section 1927(k)(1)(B)(ii) of the Act, it shall be included in AMP.

6. Inhalation, Infusion, Instilled, Implanted, and Injectable Drugs (§ 447.504(d) and § 447.507)

In accordance to section 1927(k)(1)(B)(i)(IV) of the Act, manufacturers are to exclude from the determination of AMP for a covered outpatient drug for a rebate period, any payments received from, and other discounts or rebates, that are provided to any other entity that does not conduct business as a wholesaler or retail community pharmacy. Certain specialty covered outpatient drugs are not generally dispensed through retail community pharmacies and in those instances manufacturers would be unable to generate an AMP which would prevent rebate calculations for those drugs. Section 202 of the Education, Jobs and Medicaid Funding Act (Pub. L. 111–226), enacted August 10, 2010, amended the Affordable Care Act definition of AMP at section 1927(k)(1) of the Act to include sales for the 5i drugs that are not generally dispensed through retail community pharmacies. This provision was added to ensure that an AMP could be calculated and Medicaid rebates could be collected from manufacturers for the 5i drugs that are not generally sold at retail community pharmacies. (See 156 Cong. Rec. S6766 (Aug. 5, 2010)).

This provision went into effect on October 1, 2010 and revises a manufacturer's AMP calculation for the 5i drugs to include entities other than retail community pharmacies that dispense such drugs.

While the enactment of this legislation addressed the need to ensure that rebates would be collected for these 5i drugs that are "not generally dispensed through retail community pharmacies," it also raised additional issues that were not directly addressed in the statute. Based upon section 1927(k)(1)(B)(i)(IV) of the Act, we have identified the following issues that would require further clarification: (1) Identification of 5i drugs, (2) clarification of the term "not generally dispensed," (3) determination of sales, discounts and rebates included in the 5i calculation, and (4) identification of other entities included in the definition.

We also received requests from manufacturers and pharmacies requesting guidance on this provision; specifically regarding how to interpret "not generally dispensed through a retail community pharmacy" and how to identify these 5i drugs.

We considered issuing a list identifying the specific 5i drugs that are to be included in this category. Second, we considered how to define the term "not generally dispensed." Finally, we considered clarifying which sales, discounts, and other financial transactions would be included in the determination of AMP for these drugs.

Based on our understanding of the market as well as other Federal programs, we believe most 5i drugs are administered parenterally or through an item of durable medical equipment (DME) and often require physician supervision during administration. We considered defining each type of administration route; however, we believe that it is not necessary to define the terms because the terms are essentially self explanatory. We are seeking comments on this decision.

We considered using the Medicare Part B standards to identify 5i drugs, given that Medicare Part B covers a limited number of outpatient prescription drugs that are not usually self-administered, such as those given in a hospital outpatient department or doctor's office. In addition, Medicare Part B covers outpatient prescription drugs provided through an item of durable medical equipment, such as an infusion pump or nebulizer, and injectable drugs administered by a licensed medical practitioner, if considered reasonable and necessary.

Medicare Part B does not have a comprehensive, all inclusive list of covered inhalation, infusion, injectable, instilled, or implanted drugs. However, it already has a publicly available reference which lists drugs that are "not usually self-administered" and could be considered for coverage under Medicare Part B. In addition, the Medicare Part B ASP NDC–HCPCS Crosswalk file identifies drugs that could be considered for coverage under Medicare Part B; it is publically accessible on the CMS Web site at *http://www.cms.gov/McrPartBDrugAvgSalesPrice/01a19_2010aspfiles.asp* and is updated on a quarterly basis. The Medicare Part B ASP NDC–HCPCS Crosswalk file also includes drugs which do not meet the 5i criteria, specifically those oral drugs covered by Part B following a transplant as well as Part B oral anti-emetics and oral cancer drugs. We considered using the Medicare Part B ASP NDC–HCPCS Crosswalk file to identify 5i drugs. However, we believe it would not be optimal because it is not an all inclusive list of inhalation, infusion, instilled, implanted and injectable drugs and therefore would likely miscategorize some 5i drugs.

We also considered whether CMS or the manufacturers should determine which drugs qualify as a 5i drug. In doing so, we considered whether or not it would be difficult for manufacturers to determine which drugs should be classified as an inhalation, infusion, instilled, implanted, or injectable drugs for the determination of AMP using the route of administration approved by the FDA or based upon the drug's NDC.

We also considered if we should identify the 5i drugs based upon their NDC number. If we were to identify the 5i drugs, we determined it would not provide reliable data and still require us to make available, as well as continuously update, a set of guidelines that would likely require an outside data source. In addition to the nuances of identifying existing drugs, it would be a continuous challenge to maintain a reliable list due to an evolving marketplace with the introduction of new drugs and removal of existing drugs.

Although we determined it would not be practical for CMS to provide a list identifying the 5i drugs, we considered providing a list of routes of administration as identified by the FDA that we believe would be applicable for 5i drugs. We believe this list would serve as a guide that manufacturers would use to determine if a drug could be considered as a 5i drug. We are proposing to add § 447.507 Identification of 5i drugs to indicate how 5i drugs are to be identified. In § 447.507(a) we propose to use the FDA's Routes of Administration as a guide to identify 5i drugs. Below is a list of FDA routes of administration that we are proposing manufacturers use to identify 5i drugs. It includes, but is not limited to, the routes of administration listed in Table 3. This list comes from the FDA Structured Product Labeling, Route of Administration data standards located at *http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162034.htm.*

TABLE 3—ROUTES OF ADMINISTRATION FOR 5I IDENTIFICATION

Auricular (Otic)	Intracavernous
Conjunctival	Intracavitary
Endocervical	Intracerebral
Endosinusial	Intracisternal

TABLE 3—ROUTES OF ADMINISTRATION FOR 5I IDENTIFICATION—Continued

Endotracheal	Intracomeal
Epidural	Intracoronal, Dental
Extra-Amniotic	Intracoronary
Hemodialysis	Intracorporus Cavernosum
Infiltration	Intradermal
Interstitial	Intradiscal
Intra-Abdominal	Intraductal
Intra-Amniotic	Intraduodenal
Intra-Arterial	Intradural
Intra-Articular	Intraepicardial
Intrabiliary	Intraepidermal
Intrabronchial	Intraesophageal
Intrabursal	Intragastric
Intracardiac	Intragingival
Intracartilaginous	Intrahepatic
Intracaudal	Intraileal
Intralesional	Iontophoresis
Intralingual	Irrigation
Intraluminal	Laryngeal
Intralymphatic	Nasal
Intramammary	Nasogastric
Intramedullary	Ophthalmic
Intrameningeal	Parenteral
Intramuscular	Percutaneous
Intranodal	Periarticular
Intraocular	Peridural
Intraomentum	Perineural
Intraovarian	Periodontal
Intrapericardial	Rectal
Intraperitoneal	Respiratory (Inhalation)
Intrapleural	Retrobulbar
Intraprostatic	Soft Tissue
Intrapulmonary	Subarachnoid
Intraruminal	Subconjunctival
Intrasinal	Subcutaneous
Intraspinal	Subgingival
Intrasynovial	Submucosal
Intratendinous	Subretinal
Intratesticular	Transendocardial
Intrathecal	Transmucosal
Intrathoractic	Transplacental
Intratubular	Transtracheal
Intratumor	Transtympanic
Intratympanic	Ureteral
Intrauterine	Urethral
Intravascular	Vaginal
Intravenous	
Intraventricular	
Intravesical	
Intravitreal	

We propose that manufacturers identify 5i drugs based upon the FDA route of administration list that we have provided. We are interested in comments on this proposal, including comments regarding other FDA routes of administration that could be used to identify 5i drugs that are not reflected on the provided list.

We believe that by utilizing the FDA route of administration, manufacturers will be readily able to identify products which are inhaled, infused, instilled, implanted, and injected as the information is readily available. However, manufacturers would need to determine if those products identified as 5i drugs are "not generally dispensed through a retail community pharmacy". Therefore, we also considered how to establish a standard by which manufacturers would determine when a drug is "not generally dispensed through a retail community pharmacy."

We considered adopting the Medicare Part B guidelines used to determine if a drug is to be classified as self-administered as a way to determine when a drug is "not generally dispensed" through a retail community pharmacy. In accordance with section 1861(s)(2)(A) and 1861(s)(2)(B) of the Act, the Medicare Benefit Policy Manual, Chapter 15—Covered Medical and Other Services, § 50.2(C) provides guidance regarding the term "usually." Specifically, it provides that the term is used to mean more than 50 percent of the time in determining when a drug is to be classified as self-administered. In light of this guidance, we believe that if a drug can be self administered, it is reasonable to assume that it is usually dispensed through a retail community pharmacy; however, for physician-administered drugs, we believe it is reasonable to conclude that the drug may be provided by physicians or other licensed practitioner in a variety of entities (such as clinics and physician's offices), and given the nature of the drugs, are usually not dispensed by a retail community pharmacy.

If we were to adopt a similar 50 percent methodology for determining when a drug is not generally dispensed through a retail community pharmacy, it would mean that a drug would be classified as "not generally dispensed" through a retail community pharmacy if more than 50 percent of the sales were to an entity other than a wholesaler for distribution to retail community pharmacies or retail community pharmacies that purchase drugs directly from the manufacturer. We believe that if we were to adopt a 50 percent methodology, some 5i drugs which are self-administered and generally dispensed through retail community pharmacies would be included in the alternate 5i AMP calculation due to the breadth of the percentage allowed in this calculation methodology.

We also considered whether we could use the methodology commonly used by manufacturers to calculate the Department of Veterans Affairs (DVA) non-Federal Average Manufacturer Price (non-FAMP). This methodology is described in the draft "Amended Master Agreement",[2] between the Secretary of Veterans Affairs and the Manufacturer in section VII of this Agreement. Manufacturers, manufacturer associations, pharmacies and pharmacy associations have repeatedly referred to this draft "Amended Master Agreement" when requesting guidance from CMS on the issue of defining "not generally dispensed". According to the definition of Wholesaler found in the draft "Amended Master Agreement," manufacturers are to consider a buyer to be a wholesaler when drugs with unit sales of 90 percent or greater are to retailers, other merchants, industrial, institutional or commercial users. Manufacturers are responsible for using this 90 percent principle as a guideline to determine when their sales are to wholesalers in their determination of non-FAMP. We considered whether it would be reasonable to apply the same principle to 5i drug determinations as to when a drug is "not generally dispensed" through a retail community pharmacy. We considered adopting a similar 90 percent principle because the definition of AMP, as specified in section 1927(k)(1)(B) of the Act, as revised by the Affordable Care Act, reflects sales to wholesalers for drugs distributed to retail community pharmacies (and retail community pharmacies that purchase drugs directly from the manufacturer). Therefore, for 5i drugs, our understanding of the 90 percent principle would be that if 90 percent or more of the manufacturer's sales for the respective drug were to an entity other than a wholesaler for distribution to retail community pharmacies or retail community pharmacies that purchase drugs directly from the manufacturer, then the drug would be classified as "not generally dispensed" through a retail community pharmacy.

We believe providing a quantitative method to determine when a drug is "not generally dispensed" through a retail community pharmacy would be preferable to a more qualitative drug specific approach as it provides a more definitive meaning to the term "not generally dispensed" through a retail community pharmacy. Therefore, in this proposed rule, we propose at § 447.507(b)(1) to use the 90 percent principle to determine when a drug is not generally dispensed through a retail community pharmacy. However, we continue to have some concerns regarding whether the 90 percent threshold is reasonable because it might result in a portion of drugs eligible for

[2] While the Amended Master Agreement (9/7/00 draft) between the Secretary of Veterans Affairs and the Manufacturer Identified in Section VIII of this Agreement has not been finalized and is therefore not an official DVA document, it is our understanding that it is still utilized by those in the industry when determining non-FAMP.

the 5i alternate AMP calculation to be omitted from AMP because the percentage of sales required to classify a drug as "not generally dispensed through a retail community pharmacy" may be too high. Manufacturers that enter into and have in effect a Medicaid drug rebate agreement, as set forth in section 1927(a) of the Act, are responsible for reporting AMP on a monthly and quarterly basis. Therefore, we propose at § 447.507(b)(2) that the determination of a 5i drug's status as "not generally dispensed" through a retail community pharmacy will need to be evaluated on a monthly and quarterly basis. We invite comments on this approach, including comments indicating if we should consider other quantitative options (for example, 75 percent, or 50 percent) to identify if a 5i drug is "not generally dispensed" through a retail community pharmacy and reasons as to why those options would be appropriate. We also invite comments on whether manufacturers should evaluate the status of a 5i drug's status as "not generally dispensed" through a retail community pharmacy on a monthly or quarterly basis.

We further propose at § 447.504(d) that, in light of section 1927(k)(1)(B)(i)(IV) of the Act, AMP for these drugs will include all sales, rebates, discounts, or other financial transactions already proposed for inclusion in the determination of AMP as well as the sales, rebates, discounts, or other transactions concerning these drugs, that are provided to the following non-retail community pharmacy entities:

- Direct sales to physicians.
- Sales to pharmacy benefit managers, including their mail order pharmacy's purchases.
- Sales to HMOs, including MCOs.
- Sales, discounts, or rebates paid directly to insurers.
- Sales to hospitals.
- Sales to clinics and outpatient facilities.
- Sales to mail order pharmacies.
- Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities.
- Sales to hospices.
- Sales to other manufacturers who conduct business as wholesalers or retail community pharmacies.

7. Further Clarification on the Calculation of AMP—§ 447.504(e)

a. Chargebacks and Other Discounts (§ 447.504(e)(1))

We propose that chargebacks must be included in the calculation of AMP, except for those chargebacks provided to any of the entities that are excluded from the determination of AMP. Inasmuch as we believe chargebacks are based on identified sales to a specific entity, a manufacturer cannot make assumptions regarding these chargebacks and must identify them to included or excluded AMP sales. Additionally, we propose that AMP is to include cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, incentives, administrative fees, service fees (other than bona fide service fees), distribution fees, and any other rebates, discounts or other financial transaction, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to retail community pharmacies.

b. Quarterly AMP (§ 447.504(e)(2))

Based on prior experience and on the MDR program submissions we believe that the quarterly AMP should be calculated as a weighted average of the monthly AMPs in the quarter. We believe that, based on our prior experience and the similarities of both calculations, this approach will minimize discrepancies between the monthly and the quarterly AMPs. Therefore, we propose that quarterly AMP is to be calculated as a weighted average of monthly AMPs in the quarter.

c. Manufacturer Adjustments (§ 447.504(e)(3))

To account for discounts, rebates or other price concessions that may not be available during the rebate reporting period, we propose that the manufacturer must adjust the AMP for the applicable rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized, to the extent that these discounts, rebates or arrangements are not excluded from the determination of AMP by statute or regulation.

D. Determination of Best Price (§ 447.505)

1. Definitions of Best Price and Providers

We are proposing re-codifying the terms "best price" and "Providers" under newly proposed § 447.505(a). Additionally, we are proposing to revise the definition of the term "best price" at newly proposed § 447.505(a) so that it is consistent with the definition of best price found in section 1927(c)(1)(C) of the Act.

2. Prices Included in Best Price

We believe that revising the definition of best price to be consistent with the definition provided in the statute provides sufficient detail as to which prices are to be included in the determination of best price. Therefore, we further propose the "Prices included in best price," currently located in regulations at § 447.505(c)(1)–(11), be redesignated to § 447.505(b) and that it would be revised to remove the list of prices included in best price. Instead, the paragraph would read as follows: "Except for those prices identified in paragraph (c) of this section, best price for covered outpatient drugs includes all prices and associated rebates, discounts, or other transactions that adjust prices either directly or indirectly."

3. AMP Methodology Applied to Best Price

In order to provide consistency between the AMP and best price sections, where applicable, we are proposing to apply the same methodology to best price that we are applying to AMP. This will be accomplished by making the following revisions to the prices exempt from best price section. We propose the "Prices excluded from best price," currently located in regulations at § 447.505(d)(1)–(13), be redesignated to § 447.505(c)(1)–(18). The current list of prices excluded from best price would be expanded to include three new price exclusions not currently identified in regulations. They are (1) manufacturer vouchers, (2) manufacturer-sponsored patient refund/rebate programs and (3) sales outside of the United States. These terms have been discussed earlier in the Determination of AMP section and the addition of them to the prices excluded from best price serves to align best price and AMP. We also propose to revise the phrasing of several of the existing prices listed in the "prices excluded from best price" section so they are consistent with the phrasing of the same items listed in the "sales excluded from the determination of AMP" section of the regulation. These changes do not alter the meaning or intention of the section, and applies the same treatment of sales, prices and discounts, where applicable, to best price that we are applying to AMP.

4. 340B Expanded List of Covered Entities Exempt From Best Price

In accordance with section 7101 of the Affordable Care Act, we are proposing to clarify how manufacturers are to treat orphan drugs sold to new covered entities described in sections 340B(a)(4)(M), (N) and (O) of the PHSA for best price. The Affordable Care Act expanded the list of entities eligible to enroll in the 340B drug pricing program to include certain children's hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. Additionally, the Affordable Care Act amended the PHSA by excluding certain orphan drugs from being considered covered outpatient drugs for these newly covered entities. Section 204 of the Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111–309) excludes certain children's hospitals from this exclusion, effective as if included in the enactment of section 2302 of the HCERA of 2010. In accordance with sections 1927(a)(5)(B) and 1927(c) of the Act, we propose that manufacturers can exclude only drugs purchased under the 340B Drug Pricing program from their best price calculation where the covered entities meet the conditions set by PHSA. We believe there may be circumstances in which covered entities purchase drugs outside of the 340B program, such as instances when drugs are purchased for inpatient use, drugs that have both inpatient and outpatient uses, and when a covered entity purchases drugs outside the 340B program to dispense to its Medicaid patients. In order to better understand the purchasing practices of covered entities and the scope of our proposed policy on best price, we invite comments regarding other circumstances in which covered entities purchase drugs outside of the 340B program. We believe that this position is consistent with our reading of these provisions and as a result strengthens the integrity of the MDR program because covered entities are prohibited from diverting drugs purchased under 340B authority to anyone who is not a patient of the covered entity. These requirements are proposed in a new regulation at § 447.505(c)(2)(i) and (ii).

5. Medicare Coverage Gap Discount Program (The Discount Program)

The Affordable Care Act established the Discount Program under sections 1860D–43 and 1860D–14A of the Act. The Discount Program makes manufacturer discounts available to applicable Medicare beneficiaries receiving applicable covered Part D drugs while in the coverage gap.

In general, the discount on each applicable covered Part D drug is 50 percent of an amount that is equal to the negotiated price. In accordance with the Affordable Care Act, manufacturer discounts attributed to the Discount Program will be excluded from the determination of best price as defined in § 447.505(c)(6).

E. Authorized Generics Drugs (§ 447.506)

We propose to remove the definition of "Authorized generic drugs" from § 447.506(a), as discussed in section II.B.1 of this regulation. In § 447.506(a), we propose to define the term "Primary manufacturer" to mean a manufacturer that holds the NDA of the authorized generic drug. We also propose to define the term "Secondary manufacturer of an authorized generic drug" to mean a manufacturer that is authorized by the primary manufacturer to sell the drug, but does not hold the NDA. In § 447.506(b), we propose to revise the existing paragraph to specify that sales of an authorized generic drug must be included in the AMP calculation of the manufacturer holding the NDA, referred to in this discussion as the primary manufacturer, when such drugs are being sold directly to a wholesaler. In accordance with section 1927(k)(1)(C) of the Act, we propose in § 447.506(b) to require that the primary manufacturer of an authorized generic, include in its calculation of AMP all sales of its authorized generic drug product sold or licensed to a secondary manufacturer, including transfer prices and fees paid by the secondary manufacturer to the primary manufacturer, when the secondary manufacturer is acting as a wholesaler, as set forth in section 1927(k)(11) of the Act. Additionally, the primary manufacturer holding the NDA must also include those sales in its AMP calculation that it makes directly to wholesalers including other manufacturers acting as wholesalers.

In § 447.506(c), we propose to revise the existing paragraph to specify that a primary manufacturer holding the NDA must include the best price of an authorized generic drug in its computation of best price for a single source or innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity in the United States, when such drugs are being sold by the primary manufacturer holding the NDA.

Further, we propose to add a new § 447.506(d) to specify that the secondary manufacturer of an authorized generic drug must also provide a rebate based on its sales of authorized generic drugs, and must calculate AMP and best price consistent with the requirements specified at § 447.504 and § 447.505 respectively.

F. Exclusion From Best Price of Certain Sales at a Nominal Price (§ 447.508)

Currently, the existing regulations at § 447.508(a) defines nominal sales which should be excluded from a manufacturer's best price calculation only when made to 340B covered entities as defined in section 340B(a)(4) of the PHSA, ICFs/MR, State-owned or operated nursing facilities and safety net providers or facilities/entities which the Secretary determines to be eligible.

Previously, the Secretary did not exercise the authority to add other safety net providers for which sales at nominal prices are excluded from best price. Section 221 of the Omnibus Appropriations Act, 2009, Public Law 111–8, enacted on March 11, 2009, revised section 1927(c)(1)(D) of the Act by expanding the definition of nominal priced sales to include sales of covered outpatient drugs to two new categories of entities. The expansion allows public or nonprofit entities (as defined by the Internal Revenue Service (IRS)), or State-owned or operated facilities providing the same services to the same populations as 340B(a)(4) entities of the PHSA but not funded as such and in compliance with the prohibition on abortion services as set forth in section 1008 of the PHS Act or academic health care centers providing family planning services to be eligible for the nominal priced sales.

We propose to revise § 447.508(a) to include the additional entities to which manufacturers may have nominal price sales excluded from best price. To qualify for the exception, entities must meet the criteria set forth below for either of the two new categories:

- Category 1 criteria:

+ The entity is an exempt organization as defined by section 501(c)(3) of the Internal Revenue Code of 1986; and exempt from tax under section 501(a) of such Act, or is State-owned or operated; and,

+ Provides the same type of services to the same type of populations as a covered entity described in 340B(a)(4) of the PHS Act but does not receive funding under such section.

- Category 2 criteria: The entity is a public or nonprofit entity or an entity based at an institution of higher learning, whose primary purpose is to provide health care services to students of that institution, that provides a

service or services as described under section 1001(a) of the PHS Act, 42 U.S.C. 300.

The legislation further provides that nothing in section 1927(c)(1)(D) of the Act should be construed to alter any existing statutory or regulatory prohibition on services for Category 1 entities, including the prohibition set forth in section 1008 of the PHSA.

Because these additions appear to address those nominal price sales that are not related to a manufacturer's attempt to influence market share or for other marketing reasons, we are again choosing not to identify any further entities for which manufacturer nominally priced sales would be exempt from best price.

G. Medicaid Drug Rebates (§ 447.509)

1. Determination of Rebate Amount (§ 447.509(a))

Manufacturers that participate in the MDR program are required to pay rebates for covered outpatient drugs that are dispensed to Medicaid patients. The rebates are calculated based on formulas described in section 1927(c) of the Act. As described in the "Background" section above, the Affordable Care Act made several revisions to the statutory rebate formulas. In light of these revisions, we propose to incorporate the rebate formulas into Federal regulations.

We propose in § 447.509(a)(1) that the basic rebate, for each dosage form and strength of a single source drug or an innovator multiple source drug, will be equal to the total number of units of each dosage form and strength paid for under the State plan in the rebate period multiplied by the greater of the difference between the AMP and best price of the drug or the AMP multiplied by:

- 17.1 percent for a clotting factor for which a separate furnishing payment is made under section 1842(o)(5);
- 17.1 percent for a drug approved by the FDA exclusively for pediatric indications; or
- 23.1 percent for all other single source drugs and innovator multiple source drugs.

We note that all clotting factors would not qualify for the minimum rebate percentage of 17.1 percent of AMP. Only those clotting factors for which a separate furnishing payment is made under section 1842(o)(5) of the Act would qualify as defined under the definition of clotting factors. Similarly, all drugs with pediatric indications would not qualify for the minimum rebate percentage of 17.1 percent of AMP. Only those drugs approved by the FDA exclusively for pediatric indications, in accordance with our proposed definition in § 447.502, would qualify.

We propose in § 447.509(a)(2) that the additional rebate for single source and innovator multiple source drugs will be equal to the number of units for such dosage form and strength paid for under the State plan in the rebate period multiplied by the amount, if any, by which the AMP for the dosage form and strength of the drug for the period exceeds the base date AMP for such dosage form and strength, increased by the percentage by which the CPI–U for the month before the month in which the rebate period begins exceeds such index.

We propose in § 447.509(a)(3) that the total rebate amount for single source drugs and innovator multiple source drugs will be equal to the basic rebate amount plus the additional rebate amount, if any. We also propose at § 447.509(a)(5) that in no case will the total rebate amount exceed 100 percent of the AMP of the drug.

2. Treatment of New Formulations (§ 447.509(a)(4))

The Affordable Care Act established a separate formula for calculating the unit rebate amount for a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form. For such a line extension drug, the rebate amount will be the amount calculated under section 1927 of the Act or, if greater, the product of the AMP for the line extension drug, the highest additional rebate (calculated as a percentage of AMP) under section 1927 for any strength of the original single source or innovator multiple source drug, and the total number of units of each dosage form and strength of the line extension drug paid for under the State plan in the rebate period (as reported by the State). We propose to incorporate this calculation in § 447.509(a)(4).

The statute defines a line extension for purposes of the rebate calculation as a new formulation of a drug such as an extended release formulation. However, the statute did not provide further specificity as to how line extensions should be defined. Therefore, as previously described in the definition of a line extension, we will define line extension at § 447.502. CMS plans to define a line extension drug as a single source or innovator multiple source drug that is an oral solid dosage form that has been approved by the FDA as a change to the initial brand name listed drug in that it represents a new version of the previously approved drug, such as a new ester, a new salt, or other noncovalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication for an already marketed drug. Single source or innovator multiple source drugs that receive exclusivity are not proposed to be excluded from the definition of a line extension drug. For the purpose of calculating the unit rebate amount under the Affordable Care Act, we propose that both the initial brand name drug and the line extension drug have to be an oral solid dosage form drug. We also propose to exclude a new strength of the initial brand name drug from the definition of a line extension drug. We have adopted this policy in order to capture all new formulations (including extended release formulations) and potential line extensions of single source or innovator multiple source drugs. Further, we believe this policy is consistent with our understanding of the line extension provisions in the Affordable Care Act. We invite comments from the public on this proposed policy.

We do not plan to exclude reformulations of existing products that incorporate abuse deterrent technologies from the definition of line extension drugs. The goal of these new formulations are to mitigate the risk of abuse—as opposed to the outright elimination of abuse—by preventing alternate routes of administration, or employing physical barriers that resist common methods of tampering, thus abuse deterrent formulations (ADFs) have the potential to decrease abuse of prescription drugs and improve patient and public safety. Some examples of abuse deterrent strategies that are under development include combination oral formulation products with an opioid agonist and opioid antagonist, formulations with other aversive characteristics, prodrugs, physically impenetrable formulations, and drug-device combinations with patient recognition capability. However, the statute does not exclude reformulated drugs incorporating abuse deterrent technologies from the definition of a line extension drug and thus we do not plan to exclude drugs with this labeling from the definition. The types of drugs that we are considering as line extension drugs include these reformulated products.

FDA draft guidance on the assessment of abuse potential of drugs can be found at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM198650.pdf.*

We are soliciting feedback from the industry, the public, and other

stakeholders regarding whether existing or future reformulated products incorporating an abuse deterrent technology should be subject to the additional rebate formula under the Affordable Care Act.

We have determined that we do not have the ability to identify the line extension of the initial brand name listed drug based on manufacturer rebate submissions. We consulted with the FDA to determine if the FDA currently keeps a list of line extension drugs as we have defined the term, and the FDA does not. Thus, we reviewed the drug information and data files publicly available at the FDA and propose to use the FDA's list of Chemical Types to identify the line extension drug as well as the initial brand name listed drug of the line extension drug.

The FDA classification is given to nonbiologic products during the review process and is finalized when the NDA is approved. This classification consists of Chemical Type classification, which classifies these drugs according to the type of change made to the initial brand name product. Chemical Type represents the newness of a drug formulation or a new indication for an existing drug formulation, as noted in *http://www.fda.gov/Drugs/informationondrugs/ucm079436.htm*. The FDA classifies all NDAs based on Chemical Type. One measure of innovation is the newness of the listed drug or the drug's active ingredient. The Chemical Type may identify the drug as new, or as related to the active ingredient of another drug that has already been approved.

Based on the analysis of the FDA's drug information and data files, we propose to use Chemical Types 2, 3, 4, and 6 on the FDA's list of Chemical Types below as an indicator for line extension drugs as shown in Table 4.

TABLE 4—NEW DRUG APPLICATION CHEMICAL TYPES

Number	Meaning
1	New molecular entity (NME).
2	New ester, new salt, or other noncovalent derivative.
3	New formulation.
4	New combination.
5	New manufacturer.
6	New indication.
7	Drug already marketed, but without an approved NDA.
8	OTC (over-the-counter) switch.

Chemical Type 2 (new ester, new salt, or other noncovalent derivative) represents the incorporation of different salts or esters, or other noncovalent derivatives (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance of an approved pharmaceutical ingredient into a marketed dosage form which represents a change to the listed drug (21 CFR 314.108(a)). We propose to identify this Chemical Type as a line extension because it describes a new version of the initial brand name listed drug.

Chemical Type 3 (new formulation of a previously approved drug) (not a new salt or new molecular entity) represents a change in the inactive ingredients (excipients) in a drug but no change in the amount of active ingredient. A new formulation may be a dosage form that contains the same active ingredient as was previously approved in a different dosage form as the initial brand name listed. Chemical Type 4 (new combination) represents a drug comprised of two or more components that are physically, chemically, or otherwise combined or mixed to produce a single drug product. We propose to identify this Chemical Type as a line extension because the new combination of the initial brand name listed drug of two or more active ingredients represents a new formulation of the initial brand name listed drugs that are combined to form one drug product.

Chemical Type 6 (new indication for an already marketed drug) represents a change in the description of use of an already marketed initial brand name listed drug in the prevention, treatment, or diagnosis of a recognized disease or condition. According to the National Institute for Health Care Management, research performed on drugs that are already on the market may reveal that they provide safe and effective treatments for diseases or conditions other than the indication(s) for which the product was originally approved. We propose to identify this Chemical Type as a line extension because there is an approval for a new indication that represents a change to the initial brand name listed drug.

Chemical Type 1 (new molecular entity) represents an active ingredient that has never before been marketed in the United States in any form. CMS proposes to use this Chemical Type to identify the initial brand name listed drug of a line extension.

Chemical Type 5 (new manufacturer) is assigned to an already marketed drug when it has: (1) A new manufacturer, or (2) a product that duplicates another manufacturer's already marketed drug product. We do not propose to consider this Chemical Type as a line extension because the change is a non drug-related change; rather, it is simply a transfer of the application from one manufacturer to another.

Chemical Type 7 (drug already marketed, but without an approved new drug application (NDA)) represents drugs that have not been approved by the FDA. We do not propose to consider this Chemical Type as a line extension because these drugs have not been approved by the FDA.

Chemical Type 8 (OTC (over-the-counter) switch) represents the process of transferring FDA-approved prescription medications to nonprescription, OTC status. We do not propose to consider this Chemical Type as a line extension because there is no new formulation of the initial brand name listed drug.

We plan to identify line extension drugs by using drug information that is publicly available on the FDA Web sites. As stated, CMS currently does not have the ability to identify whether a drug is a line extension and which drug is the initial brand name listed drug of the line extension drug based on manufacturers' MDRP submissions. Therefore, we plan to rely on drug information obtained from the FDA. In order for us to identify the line extension drugs using the FDA's drug information to calculate the additional rebate, there are essentially five criteria that we believe must be met. First, the line extension drug should be a single source drug or innovator multiple source drug. Manufacturers are already required to report to CMS if their nine-digit NDC drug is a single source drug, innovator multiple source drug, or non-innovator multiple source drug; therefore, we have the information to make this determination.

Second, the line extension drug has to be an oral solid dosage form of a single source drug or innovator multiple source drug in accordance with the definition of an oral solid dosage form previously provided.

Third, the line extension is identified based on Drugs@FDA's application file. Since we currently do not have the ability to identify whether the drug is the actual line extension of the initial brand name listed drug based on manufacturers' submissions, we propose to rely on the FDA's list of Chemical Types to identify which drug is a line extension drug, as described above. Because we do not approve new drugs or changes to a drug, using the Chemical Types would permit us to identify line extension drugs based on FDA data, since the FDA currently has an identifier for the Chemical Types in their Drugs@FDA's application file.

Fourth, the initial brand name listed drug of the line extension drug needs to be identified to calculate the Affordable Care Act unit rebate amount for the line extension drug. Again, as described above, we plan to use Chemical Type 1 to assist us in tracking back to the initial brand name listed drug of the line extension drug. Chemical Type 1 is assigned to an active ingredient that has not been marketed in the United States in any form; therefore, we have decided that this can be used as the initial brand name listed drug identifier. An active ingredient that has never been marketed in the United States would be approved by the FDA under a new NDA with no therapeutic equivalents, which would meet our definition of a single source drug. If there are therapeutic equivalents for the single source drug, then the drug category would change to an innovator multiple source drug in accordance with the rebate definition of an innovator multiple source drug. However, the innovator multiple source drug would retain the same NDA that was assigned to the single source drug that was first approved by the FDA. Additionally, the initial brand name listed drug has to be an oral solid dosage form per our definition of an oral solid dosage form.

Lastly, CMS currently collects drug product and pricing information by NDC, not by active ingredient. However, the FDA information is mainly available by active ingredient. Therefore, we need to identify the line extension drugs by NDC. In order for CMS to translate the active ingredient into NDC, a manual matching process has to be done to match the Drugs@FDA's application file against the FDA's Orange Book's product file: (1) To extract the Chemical Type and the application number, (2) to identify the oral solid dosage form, and (3) to obtain the FDA approval date for each drug. This file will then be matched with the FDA's NDC Directory's application and listing files to identify the NDC of each active ingredient to compile a master list of all initial brand name listed drugs and their line extension drugs by NDC. This master list will then be matched by NDC against the CMS' drug product file to identify which of CMS' NDCs are the initial brand name listed drugs and which are the line extension drugs.

Since NDCs enter and exit the MDRP frequently, we propose to update the master list based on the FDA's drug information on a quarterly basis and then match the master file against CMS' drug product file to identify new initial brand name listed drugs and new line extension drugs for the initial three quarters. Following these initial three updates, manufacturers will be responsible for identifying and reporting to CMS which of their NDCs is the initial brand name listed drug and which is the line extension drug. This is necessary to effectuate the line extension provisions of the Affordable Care Act. Additionally, as mentioned in the definition of a line extension drug, we propose that a new strength of the initial brand name listed drug would not qualify as a line extension drug. Furthermore, if we were to consider a new strength to be a line extension, it would be difficult to identify the first strength of the initial brand name listed drug because multiple strengths are often launched simultaneously and CMS would not be able to track back to the first strength of the initial brand name listed drug. We invite comments from the public on all aspects of this proposed policy.

We also do not plan to exclude a single source or innovator multiple source drug that receives 3-year exclusivity, pediatric exclusivity, or 7-year orphan drug exclusivity from the definition of a line extension drug. Drug manufacturers may separately obtain a 3-year exclusivity or a pediatric exclusivity. Drug manufacturers can reformulate a drug before it goes off patent by developing a new formulation such as a time-release version or by combining it with another existing drug, marketing it for another illness, or claiming a patent on an inactive ingredient. The 3-year exclusivity protection as indicated in sections 505(c)(3)(D)(iii), (c)(3)(D)(iv), (j)(5)(D)(iii), and (c)(5)(D)(iv) of the FFDCA, and at 21 CFR 314.108 is granted for a drug product that contains an active moiety that has been previously approved, when the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the application. This exclusivity requires conducting new clinical studies that are judged to be essential for approval of the change. Changes to a drug that qualify for this exclusivity are changes that we are considering for the definition of a line extension drug.

According to section 505A of FFDCA (Food and Drug Administration Modernization Act (FDAMA) and Best Pharmaceuticals for Children Act (BPCA), drug manufacturers can also apply for a pediatric exclusivity, which permits certain applicants to obtain an additional 6-month period of exclusivity on the use of a drug moiety in pediatric patients. We do not plan to exclude drugs that have this exclusivity from the definition of line extension drugs.

According to sections 526–527 of FFDCA and regulations at 21 CFR 316, drug manufacturers can apply for a 7-year orphan drug exclusivity. Orphan drug exclusivity promotes research and marketing for the development of drugs to treat rare diseases, defined as a disease affecting 200,000 or fewer patients in the United States, by granting a 7-year protection against competition for the designated orphan indication. We do not plan to exclude drugs that have this exclusivity from the definition of line extension drugs.

For the purpose of calculating the unit rebate amount (URA) for the line extension drug, the highest additional rebate as added by the Affordable Care Act for a line extension shall be referred to as the Alternative URA. We propose to interpret section 1927(c)(2) to provide that the URA determination is based on the greater of the Standard URA calculated under section 1927 of the Act without regard to the alternative rebate calculation provided in the Affordable Care Act, or the Alternative URA for the line extension drug under the Affordable Care Act. As previously stated, to effectuate the line extension provisions of the Affordable Care Act, we propose that both the initial brand name listed drug and the line extension drug are reported to CMS under the MDR program for the purpose of calculating the URA for a line extension drug.

Additionally, to calculate the Alternative URA, the line extension drug should be tracked back to the initial brand name listed drug. We recognize that there are multiple issues when it comes to tracking the line extension back to the initial brand name drug, such as when the line extension drug and the initial brand name listed drug are marketed by two different manufacturers or when the initial brand name listed drug has been terminated from the Medicaid drug rebate program. However, in accordance with the statute, manufacturers are responsible for calculating the Alternative URA for their line extension drugs.

We propose that when the initial brand name listed drug has been terminated that manufacturers should not be responsible for calculating the Alternative URA. The initial brand name listed drug must be active in the Medicaid drug rebate program to calculate the Alternative URA. We propose that we would calculate the URA for line extension drugs and will provide this amount to States on the quarterly rebate tape as in the current rebate process. However, in accordance with the current process, manufacturers are responsible for calculating and

making rebate payments to each State Medicaid Agency. Therefore, manufacturers are responsible for ensuring that all necessary product and pricing data, whether such information is for the initial brand name listed drug or the line extension drug, are exchanged between the manufacturer of the initial brand name listed drug and the manufacturer of the line extension drug to accurately calculate the URA for the line extension drug and provide rebates in accordance with the statute.

As provided in § 447.509(a)(5), section 2501(e) of the Affordable Care Act added section 1927(c)(2) of the Act to cap the URA at 100 percent of AMP for all brand name drugs. Therefore, this cap will also apply to the URA calculation for the line extension drugs as well.

Below are the proposed steps outlining how we plan to calculate the URA for a line extension drug. For clarification purposes, the highest additional rebate as added by the Affordable Care Act for a line extension shall be referred to as the "Alternative URA" and the URA calculation based on section 1927 of the Act (without regard to the alternative rebate calculation provided in the Affordable Care Act) shall be referred to as "Standard URA."

Step 1—Standard URA = Basic Rebate Amount + Additional Rebate Amount

Step 2—The Alternative URA is calculated as the product of the AMP of the line extension that is an oral solid dosage form and the highest additional rebate (calculated as a percentage of AMP) for any strength of the original drug.

Step 3—URA = The greater of (1) Standard URA or (2) the Alternative URA.

Step 4—Determine if the URA is greater than 100 percent of AMP.

a. If the URA is greater than 100 percent of AMP, then the URA = AMP.

b. If the URA is less than 100 percent of AMP, then use the calculated URA.

Below is an example of calculating the URA for a line extension drug.

Baseline AMP (line extension) = 100.00
AMP (line extension) = 300.00
Best Price (line extension) = 250.00
Baseline CPI–U = 170.00
CPI–U = 200.00

Step 1—Calculate Standard URA
Greater of
a. AMP × 23.1% = 300.00 × 23.1% = 69.30
or
b. AMP − Best Price = 300.00 − 250.00 = 50.00
The greater of the two results (69.30 or 50.00) is 69.30
Basic Rebate Amount for the line extension drug = 69.30
Additional Rebate Amount calculated under section 1927 of the Act Formula: If the [(Baseline AMP/Baseline CPI–U) × CPI–U] is less than the quarterly AMP, subtract [(Baseline AMP/Baseline CPI–U) × CPI] from the quarterly AMP to determine the additional URA. If the [(Baseline AMP/Baseline CPI–U) × CPI] is equal to or greater than the quarterly AMP, the additional URA is equal to zero.
[(Baseline AMP/Baseline CPI–U) × CPI–U] = 100/170 × 200 = 0.5882 × 200 = 117.65
117.65 is less than 300.00; then, 117.65 is subtracted from 300.00, 300.00 − 117.65 = 182.35
Additional Rebate Amount under section 1927 = 182.35
Standard URA = 69.30 + 182.35 = 251.65

Step 2—Calculate the Alternative URA
AMP (line extension) = 300.00
AMP (initial brand name listed drug) strength A = 280.00
AMP (initial brand name listed drug) strength B = 275.00
AMP (initial brand name listed drug) strength C = 270.00
Additional Rebate Amount (initial brand name listed drug) strength A = 200.00
Additional Rebate Amount (initial brand name listed drug) strength B = 125.00
Additional Rebate Amount (initial brand name listed drug) strength C = 110.00
Strength A additional rebate amount ratio = 200/280 = 0.7143
Strength B additional rebate amount ratio = 125/275 = 0.5636
Strength C additional rebate amount ratio = 110/270 = 0.4074
Highest additional rebate (calculated as a percentage of AMP) for any strength of the initial brand name listed drug = 0.7143
Alternative URA = Product of the AMP of the line extension that is an oral solid dosage form and the highest additional rebate (calculated as a percentage of AMP) for any strength of the original drug
Alternative URA = 300 × 0.7143 = 214.29

Step 3—URA of the line extension drug = the greater of
(1) Standard URA = 251.65 or
(2) Alternative URA = 214.29
URA of the line extension drug = 251.65
Step 4—Determine if the URA is greater than 100 percent of AMP.
AMP (line extension) = 300.00 = 100% × 300.00 = 300.00
URA = 251.65
URA is less than 100 percent of AMP; therefore, URA is equal to 251.65

3. Rebates for Drugs Dispensed Through Medicaid Managed Care Organizations (MCOs) (§ 447.509(b))

From the inception of the MDR program, section 1927(j)(1) of the Act exempted participating manufacturers from paying drug rebates for drugs dispensed to individuals enrolled in MCOs. The Affordable Care Act eliminated this exemption. Effective March 23, 2010, section 1927(b) of the Act, as amended by section 2501(c) of the Affordable Care Act requires manufacturers that participate in the drug rebate program to pay rebates for drugs dispensed to individuals enrolled with a Medicaid MCO if the MCO is responsible for coverage of such drugs. The requirement to collect rebates beginning March 23, 2010 is irrespective of any existing contracts States may have with MCOs. To comply with this section of the law and to assure that States fully collect these increased rebates, States must obtain utilization data from each Medicaid MCO in order for States to request quarterly rebates from manufacturers as well as report it in their quarterly utilization reports to CMS. This data reporting will also have other quality-related benefits for States and the Medicaid program in terms of providing timely information on drug utilization.

Section 2501(c) of the Affordable Care Act also amended section 1903(m)(2)(A) of the Act, effective March 23, 2010, by adding new conditions for Federal financial participation for MCO contracts including that:

- Any covered outpatient drug provided by the MCO is eligible for the rebates authorized under section 1927 of the Act;
- MCO capitation rates will be based on actual cost experience related to rebates and subject to Federal regulations at § 438.6 regarding actuarial soundness of capitation payments; and
- The MCO must report to the State information on the total number of units of each dosage form, strength and package size by NDC of each covered outpatient drug dispensed to Medicaid MCO enrollees and such other data that the Secretary determines necessary for the State to access the rebates authorized by this provision.

Section 2501(c) also made a conforming amendment to section 1927(j)(1) of the Act, effective March 23, 2010, to specify that certain covered outpatient drugs in this section are not subject to the rebate requirements if such drugs are both dispensed by health maintenance organizations (HMOs), including Medicaid MCOs that contract under section 1903(m), and are subject to discounts under section 340B of the Public Health Service Act.

In accordance with these revisions to sections 1927 and 1903 of the Act, we propose a new § 447.509(b). In § 447.509(b)(1), we propose to require participating manufacturers to pay rebates for covered outpatient drugs dispensed to individuals enrolled in Medicaid MCOs if the MCO is responsible for payment for such drugs. In § 447.509(b)(2), we propose that manufacturers are exempt from the requirement in paragraph (b)(1) if such drugs are dispensed by health maintenance organizations, including MCOs that contract under section 1903(m) of the Act, and subject to

discounts under section 340B of the PHS Act. In § 447.509(b)(3), we propose that a Medicaid MCO that is responsible for covered outpatient drugs dispensed to Medicaid beneficiaries must submit a report to the State within thirty days of the end of each quarter. We also propose the specific data that MCOs must include in such reports. It is expected that the States will ensure that the MCOs comply with providing timely utilization data to meet the State reporting requirements.

4. Federal Offset of Rebates (§ 447.509(c))

Section 2501(a)(2) of the Affordable Care Act added section 1927(b)(1)(C) of the Act, which provides that, effective January 1, 2010, the amount of the savings resulting from the increases in the rebate percentages described above will be remitted to the Federal government. These offset amounts are in addition to the amounts applied as a reduction under section 1927(b)(1)(B) of the Act.

We propose to calculate the offset as described below.

For single source or innovator multiple source drugs that are subject to a minimum rebate percentage of 23.1 percent of AMP:

- If the difference between AMP and best price is less than or equal to 15.1 percent of AMP, then we propose to offset the full 8 percent of AMP (the difference between 23.1 percent of AMP and 15.1 percent of AMP).
- If the difference between AMP and best price is greater than 15.1 percent of AMP but less than 23.1 percent of AMP, then we propose to offset the difference between 23.1 percent of AMP and AMP minus best price.
- If the difference between AMP and best price is greater than or equal to 23.1 percent of AMP, then we propose to not take any offset amount.

For single source or innovator multiple source drugs that are blood clotting factors and drugs approved by the FDA exclusively for pediatric indications that are subject to a rebate percentage of 17.1 percent of AMP:

- If the difference between AMP and best price is less than or equal to 15.1 percent of AMP, then we propose to offset the full 2 percent of AMP (the difference between 17.1 percent of AMP and 15.1 percent of AMP).
- If the difference between AMP and best price is greater than 15.1 percent of AMP but less than 17.1 percent of AMP, then we propose to offset the difference between 17.1 percent of AMP and AMP minus best price.
- If the difference between AMP and best price is greater than or equal to 17.1 percent of AMP, then we propose to not take any offset amount.

In the September 28, 2010 State Medicaid Director (SMD) letter, #10–019, we stated that for a drug that is a line extension of a brand name drug that is an oral solid dosage form, we planned to apply the same offset calculation as described above to the basic rebate. Further, we planned to offset only the difference in the additional rebate of the reformulated drug based on the calculation methodology of the additional rebate for the drug preceding the requirements of the Affordable Care Act and the calculation of rebates for the reformulated drug, if greater, in accordance with the Affordable Care Act. If there is no difference in the additional rebate amount in accordance with the Affordable Care Act, then we do not plan to take any offset amount. (A copy of the SMD letter can be found at *http://www.cms.gov/smdl/downloads/SMD10019.pdf.*)

However, after further review of the offset provisions in section 2501 of the Affordable Care Act, we have decided to reconsider our instructions regarding the calculation of the offset provisions for line extension drugs to reflect the difference between the URA for the drug calculated based on the applicable rebate percentage in section 1927 of the Act prior to the Affordable Care Act and the calculation of the URA for the line extension drug, if greater, in accordance with the Affordable Care Act. If there is no difference between the URA for the line extension drug based on the Affordable Care Act and URA calculation based on the applicable rebate percentage in section 1927 prior to the Affordable Care Act, then we do not plan to take any offset amount. If there is a difference then we will offset the amount of that difference.

For noninnovator multiple source drugs, we plan to offset an amount equal to 2 percent of the AMP (the difference between 13 percent of AMP and 11 percent of AMP) since these drugs are unaffected by best price.

For covered outpatient drugs that are dispensed to Medicaid MCO enrollees, we propose to offset the non-Federal share limited to the difference between the rebate percentages in effect outside of the MCO context on December 31, 2009 and the rebate percentages in effect on January 1, 2010, as described previously. Specifically, we planned for States to retain the non-Federal share of rebates below the 15.1 percent rebate percentage for single source or innovator multiple source drugs and 11 percent for noninnovator multiple source drugs as in effect on December 31, 2009. In addition, we planned for States to retain the non-Federal share of the amount above the revised minimum rebates for brand name drugs.

Additionally, we do not plan to offset the non-Federal share of any supplemental rebate States may receive above the increased Federal rebate percentages.

To ensure efficiency and uniformity, CMS plans to calculate a unit rebate offset amount (UROA) that will, on a quarterly basis, identify the amount of offset per unit of drug at the 9-digit NDC for States. The UROA will be provided to States in a manner similar to how States currently receive the URA every quarter. States will then match the UROA with the number of units of the drug for which they receive payment from a manufacturer to determine the Quarterly Rebate Offset amount (QROA) for that drug. All QROAs for all drugs of all manufacturers will then be added together to determine the Total QROA. This then will be the amount that States offset on the Quarterly Expenditure reports. Adjustments to the UROA will be treated as prior period adjustments (PPAs) and will be reported to the States the same way that URA PPAs are currently transmitted.

Please note that the offset provision would also apply to the Territories that participate in the MDR program.

H. Requirements for Manufacturers (§ 447.510)

In the Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs final rule published in the November 15, 2010 **Federal Register** (75 FR 69591), we made conforming amendments to delete references to § 447.504 "Determination of AMP" from § 447.510 "Requirements for Manufacturers". In this proposed rule, we are proposing conforming regulatory amendments to add regulatory text to § 447.510. Specifically, those references that will be added are at § 447.510(a)(1), § 447.510(c)(2)(i), and § 447.510(d)(2).

We are also proposing a conforming amendment to § 447.510(g) to clarify that the electronic format in which the product and pricing data is submitted to CMS must be submitted in a format designated by CMS.

1. Failure to Report Quarterly AMP (§ 447.510(a)(5))

In an effort to better ensure timely quarterly AMP reporting at the end of each rebate period, in accordance with the statute at section 1927(b), a manufacturer that fails to submit and certify a quarterly AMP to CMS for a

product by the 30th day after the end of each quarter will be reported to the OIG. We propose, in accordance with the statutory requirements at section 1927(b)(3)(C)(i), that manufacturer will be subject to a civil monetary penalty for each product not reported on the thirty-first day. Please see the OIG's Special Advisory Bulletin issued in September 2010 regarding reporting AMP timely, *http://oig.hhs.gov/fraud/docs/alertsandbulletins/2010/SpAdvBulletin_AMP_ASP.pdf.*

Additionally, we are considering adding regulatory guidance on suspension and termination for manufacturers that do not report quarterly AMP on a timely basis or are otherwise out of compliance with rebate requirements. We have considered a number of formal and informal administrative procedures similar to those set forth in 42 CFR part 498 or 42 CFR 430.18, which would permit an opportunity for reconsideration and administrative appeals. We are considering the appropriate terms and procedures for suspension and termination and, therefore, we invite comments from the public.

2. Reporting Revised Monthly and Quarterly AMP, Best Price, Customary Prompt Pay Discounts, or Nominal Prices (§ 447.510(b))

In this proposed rule, we propose to revise the 12-quarter rule filing limitation currently in place for manufacturers to report revisions to their quarterly AMP, best price, customary prompt pay discounts, or nominal prices. We initially established a time limit of 12 quarters for manufacturers to report revisions to their quarterly pricing data. The 12-quarter period established a time limit within which manufacturers are responsible for reporting revisions to pricing data in part to decrease associated administrative burdens on manufacturers and States. Despite the effective date of January 1, 2004 for the 12-quarter rule, we are still receiving requests from manufacturers to make revisions to the pricing data that fall outside of the 12-quarter period. Therefore, we propose that any request from manufacturers submitted to CMS to revise the monthly and quarterly AMP, best price, customary prompt pay discounts, or nominal prices that are outside of the 12-quarter filing deadline will be considered, only if it falls within one of the following categories:

- The change is a result of the drug category change or a market date change.
- The change is an initial submission for a product.
- The change is due to termination of a manufacturer from the MDR Program for failure to submit pricing data and must submit pricing data to reenter the program.
- The change is due to a technical correction (such as a keying error), that is, not based on any changes in sales transactions or pricing adjustments from such transactions.
- The change is to address specific underpayments to States, or potential liability regarding those underpayments, as required by CMS, applicable law or regulations, or an OIG or DOJ investigation.

We propose that § 447.510(b)(1) be revised to clarify that a manufacturer is required to report to CMS any revisions to correct AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12-quarters from the quarter in which the data were due. The 12-quarter limit is meant to be a specific time limit for any revision. Any revision request, except for those falling within the exceptions noted above, must be made within this 12-quarter time period. We propose to add to § 447.510(b) that any revision request that falls outside of the 12-quarter time limit will not be considered by CMS, unless it falls under the above five criteria. We also propose to revise timeframe for reporting revised monthly AMP in § 447.510(d)(3) to clarify that the only exceptions to the 36-month limit for reporting monthly AMP would be considered by CMS if it falls under the same five criteria.

We are contemplating whether to allow manufacturers that have revisions to their pricing data beyond the 12-quarter limit that meet the five criteria above to revise their pricing data on a retroactive basis: (1) Without any time limits back to beginning of the program, 1991, or (2) with some time limits outside of the 12-quarter restrictions. In other words, we are considering whether we should impose a timeframe as to how far back we should allow manufacturers to make this revision. We invite public comments on suggestions as to how far back we should allow manufacturers to make revisions to their pricing data if their request meets one of the above five exceptions.

Additionally, to ensure that any revision to pricing data is consistent across the monthly and the quarterly AMP data, if a revision request is submitted for monthly AMP and AMP units, then a revision request is also required for quarterly AMP. In addition, if a revision request is submitted for quarterly AMP, then a revision request is also required for monthly AMP and AMP units.

3. Recalculations Including Good Cause

Separate from pricing data revision request, we are proposing an option for manufacturers to submit a recalculation request outside of the 12-quarter time limit based on good cause, which would permit a manufacturer to revise its methodology for calculating AMP and best price. Our regulations at § 447.510(b) specify that manufacturers have a 12-quarter time limit to report price revisions. Manufacturers are responsible for reporting any revisions to AMP or best price within the 12 quarter limit, which begins with the quarter in which the data was due. As is the case with all pricing data submitted under the MDR program, if a subsequent review of the manufacturers' pricing data by CMS, the OIG, or another authorized government agency determines or reveals that adjustments or revisions are necessary irrespective of the quarter, the manufacturer is responsible under the statute to comply with that determination. Based on questions from manufacturers often as a result of False Claims Act concerns, we have considered allowing manufacturers to submit recalculations of AMP and best price outside of the twelve quarter time limit due to good cause. We plan to establish a good cause option to allow manufacturers to submit their pricing data due to a recalculation of the methodology for calculating AMP and best price outside of the 12-quarter time limit to address underpayments and potential liability regarding those underpayments that may extend outside of that 12-quarter period. We are considering proposing a "good cause" option to extend the time limit for filing a recalculation request, similar to that used in Medicare. We invite comments from the public on this option.

4. Base Date AMP (§ 447.510(c)(1) to § 447.510 (c)(4))

In the 2007 AMP final rule, we allowed manufacturers to report a revised base date AMP to CMS within the first four full calendar quarters following the publication date of the final rule. To differentiate between the timeframe when manufacturers were allowed to report revised base date AMPs in accordance with the DRA-based definition of AMP and the timeframe described below, we propose to revise § 447.510(c)(1) and § 447.510(c)(2) by inserting "DRA" before base date AMP where it occurs. We also propose to remove the notation "[OFR: insert publication date of the final rule]" and replace it with "July 17, 2007" in § 447.510(c)(1).

The Affordable Care Act significantly revised the definition of AMP to mean for a covered outpatient drug (including those sold under section 505(c) of the FFDCA), the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer. To reflect the changes to AMP as set forth in the Affordable Care Act, we propose to allow manufacturers to recalculate base AMP in accordance with the definition of AMP in § 447.504 of this subpart. Base AMP is used in the calculation of the additional rebate described in section 1927(c)(2) of the Act. This additional rebate is defined as the difference between the current quarterly AMP reported to CMS and the base date AMP trended forward using the CPI–U. We propose this revision so that the additional rebate would not increase solely due to the changes in the definition of AMP. We propose giving manufacturers the option to report a recalculated base date AMP based on the Affordable Care Act. We propose to allow manufacturers the option to decide whether they will recalculate and report to CMS an Affordable Care Act base date AMP in light of the revised definition of AMP or continue to use their existing base AMP. We propose to give manufacturers this option because we are aware that some manufacturers may not have the actual data needed to recalculate their base date AMP or may find the administrative burden to be more costly than the savings gained. We propose to provide manufacturers with the option to report the recalculated Affordable Care Act base date AMP for a period of four full calendar quarters beginning with the first full quarter after the publication of the final rule.

5. Calculation of Monthly AMP (§ 447.510(d)(2))

Section 1927(e)(5) of the Act specifies that the Secretary is to implement a smoothing process for AMP, which shall be similar to the smoothing process used in determining the average sales price (ASP) of a drug or biological under Medicare Part B. The Medicare Part B regulations at § 414.804(a)(3) specify that the ASP methodology for smoothing lagged price concessions requires that manufacturers calculate the total lagged price concessions for the previous 12-month period and convert the dollar amount to a percentage of sales over that same 12-month period. This percentage is then applied to the current quarter's sales to estimate the lagged price concessions for that quarter.

Therefore, we are proposing manufacturers would be required to use a 12-month rolling percentage to estimate the value of lagged price concessions in their calculations of the monthly and quarterly AMPs.

Specifically, we are proposing that a manufacturer's monthly AMP is to be calculated based on the weighted average of the prices for all the manufacturer's package sizes of each covered outpatient drug sold by the manufacturer during a month. It is calculated as net sales divided by number of units of the drug sold, excluding goods or any other items specifically excluded in the statute or regulations. The drug unit is the lowest identifiable amount (for example, tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams) as reported by the manufacturer.

Monthly AMP should be calculated consistent with this methodology, based on the best data available to the manufacturer at the time of submission.

In calculating monthly AMP, a manufacturer should estimate the impact of its lagged price concessions using a 12-month rolling percentage to estimate the value of those discounts. Following is an example of how manufacturers would calculate the monthly AMP by using a 12-month rolling percentage to estimate the lagged price concessions:

- Total lagged price concessions over the most recent 12-month period = $150,000.
- Total sales subject to AMP reporting for the most recent 12-month period = $600,000.
- $150,000/$600,000 = 0.25 (or 25 percent).
- The result (25 percent) is the percentage manufacturers subtract from their total sales for that month to estimate lagged price concessions for that month.
- Current month sales = $50,000.
- $50,000 × 25 percent (estimated percentage of lagged price concessions) = $12,500 estimated lagged price concessions for the current month.
- $50,000 − $12,500 = $37,500 (net total sales after subtracting estimated lagged price concessions for the current month).
- Units sold during current month = 10,000 units.
- $37,500/10,000 units = $3.75 AMP.

The only differences between the proposed AMP smoothing process methodology and the ASP smoothing process methodology is that the ASP smoothing process is applied on a quarterly basis whereas the AMP smoothing process will be applied on a monthly basis and by statutory definition, the ASP calculation includes more sales than in the AMP calculation. We believe this process will result in more stable AMP calculations on a month to month basis, because the estimated lagged price concessions will increase as sales increase, and likewise as sales decrease. In addition, it meets the statutory requirement that the AMP smoothing process be similar to the smoothing process used in determining the ASP.

6. Manufacturer Reported AMP Units (§ 447.510(d)(6))

Section 2503(b) of the Affordable Care Act requires manufacturers to submit to CMS on a monthly basis the total number of units that are used to calculate the monthly AMP for each covered outpatient drug no later than 30 days after the last day of each prior month. We propose that the manufacturer report monthly AMP units as the number of units that are used to calculate the monthly AMP to be reported to CMS. Additionally, in order to be consistent and to implement the rebate and FUL provisions, the monthly units should be of the unit type that is reported as part of the product data and the unit type used in the quarterly and monthly AMP calculation for each NDC to ensure consistency in the calculation as well as the reporting of the monthly and quarterly AMP and the AMP units.

7. Failure To Report Monthly AMP and AMP Units (§ 447.510(d)(7))

Currently a manufacturer must submit a monthly AMP to CMS no later than 30 days after the last day of the prior month. Under the Affordable Care Act, a manufacturer will be required to submit the total number of units that are used to calculate the monthly AMP no later than 30 days after the last day of the prior month. To ensure that each manufacturer is reporting timely to CMS, a manufacturer that fails to submit and certify monthly AMP and the AMP Units for a product to CMS by the 30th day after the end of each month will be reported to the OIG. We propose, in accordance with the statutory requirements at section 1927(b)(3)(C)(i), that the manufacturer will be subject to civil monetary penalty for each product not reported on the thirty-first day. Please see the OIG's Special Advisory Bulletin issued in September 2010 regarding reporting AMP timely, *http://oig.hhs.gov/fraud/docs/alertsandbulletins/2010/SpAdvBulletin_AMP_ASP.pdf.*

Additionally, we are considering adding regulatory guidance on suspension and termination for manufacturers that do not report monthly AMP and AMP Units on a timely basis. As noted previously, we have considered a number of formal and informal administrative procedures similar to those set forth in 42 CFR part 498 or 42 CFR 430.18. Therefore, we invite comments on these procedures from the public.

I. Requirements for States (§ 447.511)

Section 1927(b)(2)(A) of the Act specifies that States are required to report to each manufacturer, not later than 60 days after the end of each rebate period, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed, and to promptly transmit a copy of such report to the Secretary. Effective March 23, 2010, the Affordable Care Act amended section 1927(b)(2)(A) of the Act to require that the State include in those reports, the information reported by each Medicaid MCO.

We propose a new § 447.511 to clarify the requirements for States. In § 447.511(a), we propose to list the data that the State must provide to participating drug manufacturers. We further propose that States must submit this data within 60 days after the end of each quarter.

In § 447.511(b), we propose that the States report drug utilization data as defined in § 447.511(a) to CMS on a quarterly basis.

In § 447.511(c), we propose that a State that has participating Medicaid MCOs, which includes covered outpatient drugs in its capitated arrangements with the MCOs, report data listed in §§ 447.511(a) for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the MCO and for which the MCO is responsible for coverage of such drugs under section 1903 of the Act. We further propose that this data be identified separately from the data pertaining to drugs that the State reimburses on a fee-for-service basis.

With the proposed change in the definition of "State" to include the territories, we recognize that these requirements would ultimately be applicable to the territories. We are also aware that it will take the territories time in order to upgrade their computer systems and come into compliance with the MDR program requirements. Therefore, we are proposing that the requirements discussed in this section would not be effective for the territories until one year after the first day of the first full quarter after the publication of the final rule.

J. Drugs: Aggregate Upper Limits of Payment (§ 447.512)

In the "Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs" final rule that we published in the November 15, 2010 **Federal Register** (75 FR 69591), we made conforming amendments to remove references to § 447.514 "Upper limits for multiple source drugs" from § 447.512 "Drugs: Aggregate upper limits of payment". We are proposing regulatory amendments to add those references back into the regulatory text of § 447.512.

Currently, § 447.512(b) establishes guidelines for payment levels that the agency has determined to be appropriate. At § 447.512(b)(1), we propose to replace the term "EAC" with the term "AAC" as we have previously proposed to replace "estimated acquisition cost" with "actual acquisition cost". Further, we propose to add the word "professional" to the description of dispensing fee in this section.

We are proposing these changes in terminology in part because we believe that using the AAC in determining the drug ingredient component of the reimbursement formula will be more reflective of actual prices paid, as opposed to unreliable published compendia pricing.

Currently, States usually determine EAC for single source drugs and drugs other than multiple source drugs for which either a specific Federal Upper Limit (FUL) or State maximum allowable cost (SMAC) has been established by paying the lower of:

- A percentage decrease applied to a commercially published reference price such as average wholesale price (AWP) or a percentage increase to wholesale acquisition cost (WAC), or
- The pharmacy's usual and customary charge to the public.

Using a commercially published reference price as the basis for Medicaid pharmacy reimbursement has been problematic for both the States and the Federal government. Several reports issued by the OIG have shown that AWP is often a significantly inflated price, and not necessarily reflective of a pharmacy's actual purchase price for a drug. (OIG Audit reports—A–06–00–00023, A–06–01–00053, A–06–02–00041).[3]

Further, AWP raises other concerns when used as a basis for payment, as evidenced by litigation relating to its use. See *New England Carpenters Health Benefits Fund* v. *First DataBank*, 602 F.Supp.2d 277, 279 (D.Mass. 2009) (in which the Court stated that "despite its name, AWP is not an average of prices charged by wholesalers to providers (such as pharmacies and doctors) and it does not necessarily bear any relationship to any prices actually charged in the marketplace.")

At this time the commercial compendium, First DataBank, Inc. has reported that it is scheduled to cease the publication of AWP as of September 2011. While other drug pricing compendia may publish both AWPs and WACs, we have concerns, based on the previously referenced OIG reports, that these prices will not be based on actual costs or reflect actual prices that providers pay for these drugs.

Certain States, in order to calculate more accurate payment rates, have already begun to base some of their drug prices on survey data based on pharmacy invoice prices.[4] We believe that these surveys of pharmacy providers will assist States in determining valid reference prices from which to develop drug ingredient reimbursement. Section 447.518 of this proposed regulation provides further discussion about how States can develop and justify their AAC.

K. Upper Limits for Multiple Source Drugs (§ 447.514)

Section 2503(a) of the Affordable Care Act revises the definition of "multiple source drug" established in section 1927(k)(7)(A)(i) of the Act to mean, for a rebate period, a covered outpatient drug for which there is at least one other drug product which is rated as therapeutically equivalent (under the FDA's most recent publication of the Orange Book), is pharmaceutically and bioequivalent, as determined by the FDA; and is sold or marketed in the United States during the period. We propose this definition be included in § 447.502 "Definitions." In accordance with these statutory requirements, we also propose that at least two

[3] *http://oig.hhs.gov/oas/reports/region6/60000023.htm. http://oig.hhs.gov/oas/reports/region6/60100053.htm. http://oig.hhs.gov/oas/reports/region6/60200041.htm.*

[4] Alabama-10–008, effective date September 22, 2010 (Alabama AAC Survey information available at *http://al.mslc.com/Faqs.aspx*) and Oregon-10–13, effective date January 1, 2011 (Oregon AAC Survey information available at *http://or.mslc.com/AACList.aspx* or *http://or.mslc.com/uploadedFiles/Oregon/OR%20Communications%20Plan.pdf*).

therapeutically equivalent ("A" rated) formulations must be listed in the FDA's Orange Book in order for the drug to be defined as a multiple source drug.

Also, section 2503(a) of the Affordable Care Act revised section 1927(e) of the Act to change the requirement for a FUL to be established for each multiple source drug for which the FDA has rated two or more products therapeutically and pharmaceutically equivalent, to three or more products, regardless of other formulations. In accordance with this statutory requirement, we are proposing in § 447.514(a)(1) that a FUL be established for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent. We propose that the FUL will be calculated, in accordance with section 1927(e)(4) of the Act, using only therapeutically and pharmaceutically equivalent drugs. Any other formulations of the drug listed in the FDA Orange Book that are not therapeutically and pharmaceutically equivalent to the reference listed drug, for example, "B" rated drugs, will not be used in the calculation of the FUL.

For purposes of applying this rule, we consider drug products to be therapeutically equivalent if they are identified as A-rated in the current edition of FDA's Orange book. Per the FDA's Orange Book, drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling. Drug products are considered pharmaceutical equivalents if they contain the same active ingredient(s), are of the same dosage form, route of administration and are identical in strength or concentration. In general, with limitations that may apply to particular patients, the FDA believes that products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.[5]

"B" rated drugs are drugs that FDA does not consider therapeutically equivalent to other pharmaceutically equivalent products. Per the FDA Orange Book, drug products designated with a "B" code fall under one of three main policies:

- The drug products contain active ingredients or are manufactured in dosage forms that have been identified by FDA as having documented bioequivalence problems or a significant potential for such problems and for which no adequate studies demonstrating bioequivalence have been submitted to FDA; or
- The quality standards are inadequate or the FDA has an insufficient basis to determine therapeutic equivalence; or
- The drug products are under regulatory review.[6]

Therefore, we propose that any alternative formulations not therapeutically equivalent to the reference listed product in FDA's Orange Book will not be subject to the FUL. We propose that the FUL will only be applied to those drugs that are therapeutically equivalent to the reference listed drug, that is, "A" rated drugs that are pharmaceutically equivalent to the reference listed drug; however, we are inviting comments on the issue of the FUL being applied to drugs that are not therapeutically equivalent to the reference listed drug.

In accordance with section 2503(a) of the Affordable Care Act, we are proposing that the FUL will be calculated as no less than 175 percent of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products. We plan to determine the weighted average on the basis of manufacturer submitted utilization of the most recently reported monthly AMPs for all therapeutically equivalent innovator (I) and non-innovator (N) multiple source drug products that, by definition elsewhere in this proposed rule, are available for purchase by retail community pharmacies on a nationwide basis.

In computing the FUL, we would use the monthly AMP and the monthly utilization data submitted by the manufacturer. Using the monthly AMP data will provide for the timeliest pricing data and allow revisions to the FUL list on a monthly basis. In addition, the statute requires us to use the recently reported monthly AMPs to calculate the FUL. It will also permit us to update the FULs on a timely basis in accordance with the provisions of section 1927(f)(1)(B) of the Act.

The currently reported AMP is based on the nine-digit NDC and is specific to the product code, combining all package sizes of the drug into the same computation of AMP. Inasmuch as this computation is used to determine the AMP that is currently reported by manufacturers, we propose to use this AMP for the FUL calculation.

Section 2503(a) of the Affordable Care Act redefines AMP, effective October 1, 2010. Due to this change in the determination of AMP, and the requirement that the monthly AMP under this calculation first be reported for October 2010 data, CMS received these revised monthly AMPs and utilization data beginning in November 2010. While the law required manufacturers to change their calculation of AMP effective October 1, 2010, we did not issue FULs based on this data. Further, we decided to not use data submitted before December 15, 2010 to calculate the FULs, as there was some concern within the industry that manufacturers may have based their AMP calculation on prior AMP regulations that were in effect until December 15, 2010.

In the interim, CMS has been reviewing monthly pricing data submitted and continues to work towards increasing labeler compliance of reporting data timely. When establishing a FUL, we propose to disregard the AMP of an NDC which has been terminated. We note that we have published four sets of draft FUL files on our Web site. We invited comments from stakeholders and we have posted several of those comments and our responses to those comments at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits-.html.*

In calculating the FUL, we propose to eliminate covered outpatient drugs designated as single source (S) drugs from the FUL calculation because the FUL in the statute, is based on the weighted average of AMPs for multiple source drugs, and, single source drugs are, by definition, not multiple source drugs, and should be reported according to the statute. We note here that there should be no instances of an (S) drug in a FUL group, as labelers should be reporting drugs that are therapeutically equivalent drug products as (I) drugs, and statutory provisions require us to use only multiple source drugs when calculating the FUL. We propose to rely on manufacturer submitted data in determining if a drug product is used in the calculation of the FUL, that is, if it is an (I) or an (N) drug. CMS has issued guidance previously, and more recently, requested drug labelers to review the drug category for which their NDC is reported, and if they determine that an incorrect drug category has been reported to CMS for a product, they are required to request a drug category change for the product. We have also recently reminded labelers that changing a drug category from (S) to (I)

[5] *http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf.*

[6] *Id.*, vii.

has no prior approval requirement from CMS, and that these changes can and should be made timely by the labeler via the Drug Data Reporting for Medicaid system. See Manufacturer Releases No. 80 and No. 82 (issued on January 5, 2010 and November 1, 2010, respectively). Accordingly, we propose to include pharmaceutically and therapeutically equivalent innovator multiple source and non-innovator multiple source drugs when calculating the weighted average of monthly AMPs.

In light of our experience with the implementation of section 1927 of the Act, we believe that when a drug product has at least one other FDA-approved, pharmaceutically and therapeutically equivalent drug product, the drug is generally sold or marketed on a nationwide basis. Further, we believe that when a drug product has at least two FDA-approved, pharmaceutically and therapeutically equivalent drug products, that all retail community pharmacies would be able to purchase at least one of the drug products through a pharmaceutical market channel of distribution, including, but not limited to, a national, regional, or specialty drug wholesaler, chain warehouse, group purchasing organization, or directly from the drug manufacturer. We do not believe it is necessary that each retail community pharmacy have the ability to purchase every supplier's pharmaceutically and therapeutically equivalent drug in order for the Secretary to calculate the FUL for pharmaceutically and therapeutically equivalent multiple source drug products, provided the retail community pharmacy is able to purchase at least one of the drug products. We invite comments on the issue of national availability in the context of the FUL requirements and request comments regarding specific instances where such drug products are not available for purchase by retail community pharmacies on a nationwide basis. Further, as noted previously, we will not be using the AMP of a terminated NDC to set the FUL beginning with the first day of the month after the termination date reported by the manufacturer to CMS, and a weighted average, using the monthly AMP unit data, will be used to calculate the FUL.

We further propose to establish the upper limit reimbursement at 175 percent of the weighted average of monthly AMPs in the aggregate.

We analyzed the FUL and determined that the weighted AMP multiplied by 175 percent including (I) and (N) drugs would be an adequate reimbursement methodology, per the below chart that shows the analysis of the fiscal year 2009 estimated aggregate expenditures, comparing reimbursement using the DRA AMP-based FUL methodology to the pre-DRA FUL methodology, weighted AMP FUL, weighted AMP multiplied by 175 percent, and Indiana's State Maximum Allowable Cost (IN's SMAC). Utilization data provided to CMS by States were used to calculate the total number of units reimbursed for each drug group and was multiplied by the DRA AMP-based FUL, the pre-DRA FUL, the weighted AMP FUL, the weighted AMP multiplied by 175 percent FUL, and IN's SMAC to get the aggregate limit for each drug group based on each formula used to calculate the FUL. We chose IN's SMAC as one of the formulas in our comparative analysis because IN's SMAC, in accordance with its State plan, is developed by using pharmacy invoices, and is equal to the average AAC per drug adjusted by a multiplier of at least 1.0. IN's Office of Medicaid Policy and Planning reviews the SMAC rates on an ongoing basis, and adjusts the rates as necessary to reflect prevailing market conditions and ensure reasonable access by providers to drugs at or below the applicable SMAC rate. Currently, IN adjusts their average AAC using a multiplier of 1.2. There are approximately 550 drug groups reflected in this estimated analysis. Because utilization data are reported on a quarterly basis while the DRA AMP-based FUL is generated on a monthly basis, the estimated aggregate limit is calculated for each month using the quarterly utilization data averaged out by the 3 months. This calculation was done for all four quarters of fiscal year 2009, which was then aggregated to get the fiscal year 2009 estimated aggregate expenditure for each FUL formula. Each bar represents the aggregate expenditure while the percentage amount represents the comparison to the DRA AMP-based FUL.

The estimated aggregate is calculated with the availability of at least three therapeutically equivalent drug products.

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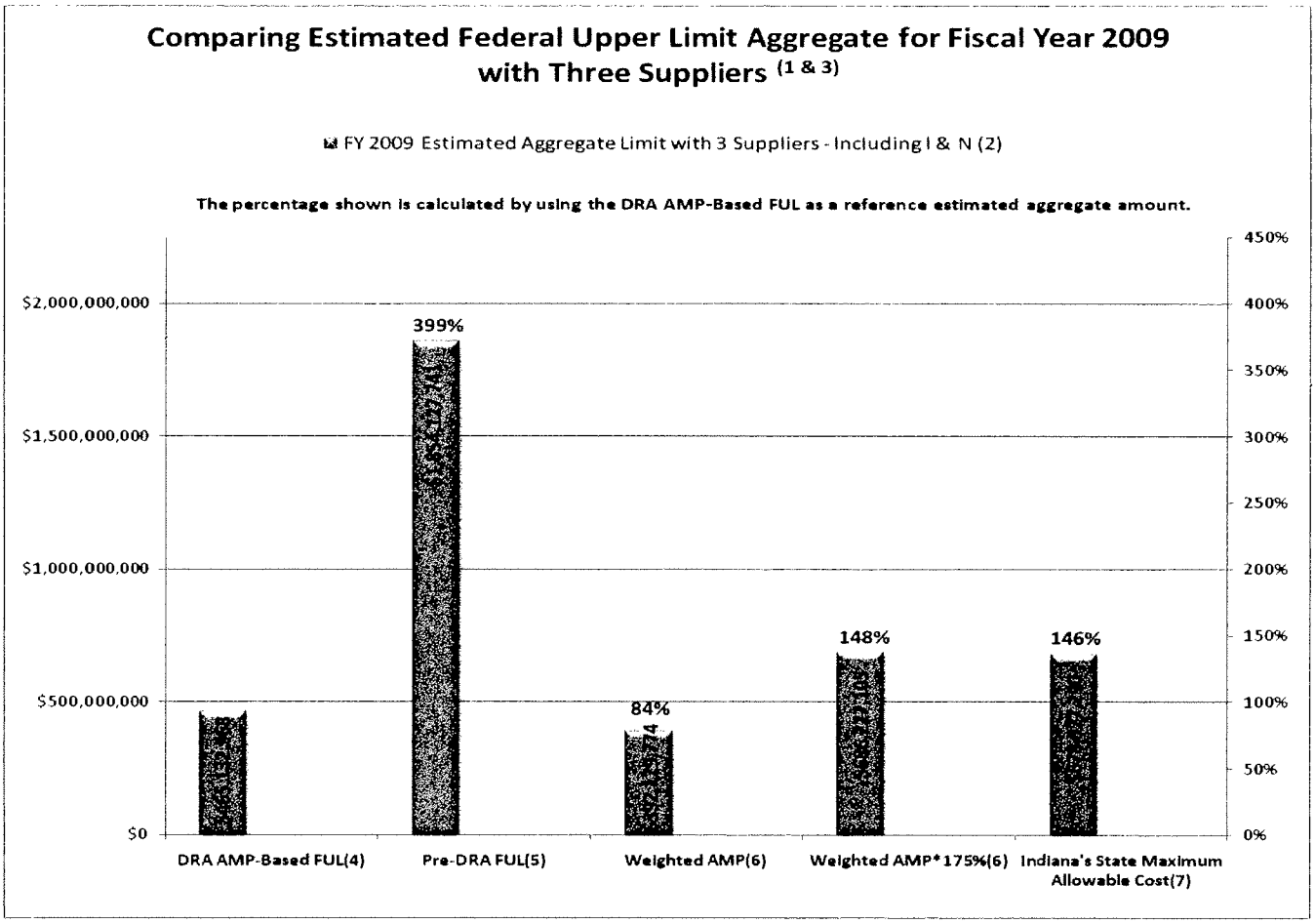

Footnotes:

1. Each FUL group is established based on the DRA criteria that if all formulations of a multiple source drug are identified as A-rated in the FDA's most current edition of "Approved Drug Products with Therapeutic Equivalence Evaluations" (including supplements or in successor publications), then there must be at least 2 A-rated versions of the drug.
2. I is for innovator multiple source drug and N is for noninnovator multiple source drug.
3. Calculations excluded drug products that were not therapeutically equivalent, had NDCs with AMP not reported, and NDCs with zero utilization. Additionally, calculation of each formula is based on the availability of three or more suppliers at the NDC-9 level and two different product codes are considered as two different suppliers.
4 DRA AMP-based FUL is based on the DRA criteria to calculate FUL, which included the availability of two suppliers and included a 40% outlier.
5. Pre-DRA FUL is based on FUL issued by CMS on September 25, 2009.
6. States' utilization data are used to calculate weighted AMP (WAMP) and the estimated aggregate limit: FY 1Q09 = 3Q08 Utilization, FY 2Q09 = 4Q08 Utilization, FY 3Q 2Q09 = 1Q09 Utilization, and FY 4Q09 = 2Q09 Utilization. An NDC is excluded if there is no utilization on that NDC.
7. Indiana State Maximum Allowable Cost effective as of October 23, 2009 was obtained from Indiana Pharmacy website, http://www.indianamedicaid.com/ihcp/PharmacyServices/list.asp. Please note that when making the determination for their State MAC, IN does not use innovator multiple source drugs.

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In a recent report issued by the Government Accountability Office (GAO) "Medicaid Outpatient Prescription Drugs: Estimated Changes to Federal Upper Limits Using the Formula under the Patient Protection and Affordable Care Act" (GAO–11–141R), the GAO found that Affordable Care Act FULs were higher than the undiscounted average retail pharmacy acquisition costs for 34 of the 40 drugs in the sample and was 35 percent higher than the sum total of the undiscounted pharmacy acquisition costs for these drugs, which would have also lowered the Medicaid expenditures on these drugs by 60 percent.

Furthermore, the GAO stated that the Affordable Care Act FULs could further exceed the retail pharmacy acquisition costs if the GAO was to take into consideration factors that were not used in the analysis of this report. The GAO stated that the acquisition cost data the GAO used do not include rebates paid by manufacturers to retail pharmacies. If included, any applicable rebates would have reduced the average retail acquisition costs for the drugs in the

sample; thus, the Affordable Care Act FULs would exceed the retail pharmacy acquisition costs by more than 35 percent. Additionally, if the Affordable Care Act FULs were to be calculated using the new AMPs based on the revised definition under the Affordable Care Act, then the Affordable Care Act FULs would have exceeded the retail pharmacy acquisition costs by even greater than 35 percent.

Therefore, based in part on the findings from the GAO report, we believe that calculating the Affordable Care Act FULs at weighted AMP times 175 percent would be a more than adequate reimbursement to the pharmacies.

The Affordable Care Act's revisions to section 1927(e)(5) of the Act allow but do not require the Secretary to calculate the FUL above the 175 percent of the weighted average of AMPs. Based on the data described above, we have decided to calculate the FUL at 175 percent. Using any percentage greater than 175 percent would further inflate the aggregate expenditures depicted on our chart. As provided in the chart above, calculating the FUL as 175 percent of the weighted AMP, including multiple source drugs, that is, I and N drugs, yields a reimbursement that is just slightly higher than Indiana's SMAC which is based on actual pharmacy acquisition data and is consistent with the GAO's findings that these levels are generally in excess of the actual acquisition cost of the drug. Because it is virtually impossible to price each drug at its actual acquisition cost to each pharmacy and reflect the changes in the marketplace at the same time they occur, the upper limit reimbursement continues to be established in the aggregate. States maintain their right to adjust reimbursement on a drug by drug basis to the extent that the State's reimbursement remains under the aggregate upper limit.

Thus, using a factor of 175 percent of weighted monthly AMPs should yield adequate reimbursement for pharmacy providers, while achieving cost savings for the Medicaid program compared to pre-DRA FULs.

L. FULs Smoothing Process

As discussed previously, section 2503(a) of the Affordable Care Act amended the FUL provision at section 1927(e)(5) of the Act to specify that the Secretary shall implement a smoothing process for AMPs which shall be similar to the smoothing process used in determining the ASP of a drug or biological under Medicare Part B. In order to ensure that the smoothing process being utilized by manufacturers is uniform and consistent with statutory requirements, as was discussed in Manufacturer Release #83, a manufacturer should estimate the impact of its lagged price concessions using a 12-month rolling percentage to estimate the value of those discounts. This guidance is restated in the preamble language of this proposed rule and would be codified in proposed regulatory text at § 447.510(d)(2).

We also considered whether to implement a further smoothing process applicable to the FUL calculation. While the statute requires us to use the most recently reported monthly AMPs to calculate the FUL, it did not address smoothing the FULs themselves. However, after reviewing the first months of the draft FULs, which we posted on our Web site, we note that there is some variability in the FULs from one month to the next. Therefore, we looked at various approaches for smoothing the FULs, as follows. We considered:

- Using the mean of the most recently reported monthly AMPs over a specific period of time; for example, three months, to minimize the variability of the monthly AMPs before weighting the monthly AMPs and multiplying the result by 175 percent to calculate the FUL;
- Using the median of the most recently reported monthly AMPs over a specific period of time; for example, three months, before weighting the monthly AMPs and multiplying the result by 175 percent to calculate the FUL;
- Weighting the most recently reported monthly AMPs over a specific period of time; for example, three months, to minimize the variability of the monthly AMPs before weighting the monthly AMPs and multiplying the result by 175 percent to calculate the FUL;
- After calculating the FUL as the weighted average of monthly AMPs in a FUL product group, calculate the mean of the FULs for each product group over a specific period of time; for example, three months, to smooth the FUL if there is variability in the calculated FUL from month to month;
- Excluding outlier monthly weighted AMPs that are less than a certain percentage of the next highest monthly AMP for therapeutically and pharmaceutically equivalent products;
- Excluding a monthly AMP if the percent change is greater than a certain percentage when compared to the last manufacturer reported and certified monthly AMP;
- Increasing the calculated FUL by a certain percentage if the FUL is less than a certain percentage from the last FUL;
- Calculating the FUL using only monthly weighted AMPs within a FUL Product Group that have a certain percentage of the market share based on the monthly AMP units reported to us by drug manufacturers.
- Using the mean of the monthly weighted average of AMPs for an entire FUL Product Group over a specific period of time; for example, three months; and/or,
- Excluding monthly AMPs that are higher or lower than the standard deviation of the mean of all the monthly AMPs in a specific FUL Product Group.

Smoothing the pricing data using one of these methodologies would prevent some month-to-month fluctuations in the FULs. However, implementing any of the smoothing methods would have limitations. For example, it could require that for the entire averaging period, all manufacturers have timely reported monthly AMP and AMP units or that we look at alternatives to that. Further, it would require us to look at how to add newly available generic drugs or other changes in circumstances that affect these FULs. We are concerned that this could skew a resultant FUL so that it would be less representative of the price at which the pharmacy could purchase that drug. For example, it could cause a FUL for a particular FUL group to be lower than if we use only one month of AMP data in the calculation depending on the reported and certified monthly AMP and AMP units over the averaging period. As such, it may not capture price increases in a drug or reflect changes in price caused by a shortage of the drug. Conversely, it could overstate the price of drugs where more manufacturers are coming into the marketplace and the price of the drug was decreasing over time.

After careful consideration, we have decided not to propose a specific methodology to smooth the FULs at this time. Because AMPs are based on prices paid to manufacturers by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer, they are subject to some fluctuations and variances in the generic drug market, which may result in fluctuations in the AMP-based FUL from month to month. Furthermore, these changes may be present even if we decide to implement a smoothing process over and above the smoothing process that manufacturers are presently using for AMP calculations. As previously mentioned, price changes

can occur as a result of product shortages, manufacturing disruptions, seasonal supply and demand, and products with a short shelf life. We are inviting comments on this issue, including the benefit of such a process, the options we considered, options we have not considered, and whether a smoothing process is necessary.

M. State Plan Requirements, Findings, and Assurances (§ 447.518)

In the Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs final rule published in the November 15, 2010 **Federal Register** (75 FR 69591), we made conforming amendments which deleted references to § 447.514 "Upper limits for multiple source drugs" from § 447.518 "State plan requirements, findings and assurances". We are proposing conforming regulatory amendments to those references and are adding them in the regulatory text of § 447.518.

In addition, to conform with the change from "estimated acquisition cost" to "actual acquisition cost", we propose in § 447.518(c) to require all States to provide data to adequately support proposed changes in reimbursement using AAC. This supporting data could include, but is not limited to, a national survey, to create a database of actual acquisition costs that States may use as a basis for determining State-specific rates. Additionally, a State survey of retail pharmacy providers or other reliable data which reflects the pharmacy provider's price to acquire a drug could be used as a basis to support proposed changes in reimbursement. We believe that surveying pharmacy providers for acquisition costs or using other reliable data, based on actual sales transactions, as a base from which to develop an appropriate ingredient cost reimbursement is reasonable. Alternatively, the use of an AMP, which is based on actual sales data and reported and certified by drug manufacturers, could be considered as a reimbursement metric. The State can also determine the relationship of the AMP to factors such as the wholesaler markup, which covers the cost of distribution and other service charges by the wholesaler, to determine a reasonable reimbursement that would appropriately compensate pharmacies for these costs.

We are inviting comments on the practicality of requiring each State to conduct a survey, the frequency of such a survey, and how closely we would expect the State to conform to the survey results in the reimbursement rates they propose in their SPA, including the use of acquisition cost averaging, AMPs as a basis for reimbursement, including the application of an appropriate markup factor or other methods of determining the ingredient cost.

Although we considered various alternatives for how AAC will apply in the case of reimbursement for covered outpatient drugs purchased under other Federal drug programs such as the 340B Drug Pricing Program and the Federal Supply Schedule (FSS) we are not proposing specific methodologies. Through these programs, certain Federal grantees and others can purchase drugs at significant discounts, and these drugs will then be reimbursed through the State Medicaid program for Medicaid beneficiaries. Under current HRSA policy, participating covered entities are permitted to dispense drugs purchased outside of 340B authority for their Medicaid patients, often referred to as the "Medicaid carve out" option. In accordance with section 340B(a)(5) of the PHS Act and section 1927(a)(5)(C) of the Act, a covered entity is not permitted to seek Medicaid payment for a drug that is subject to discounts under the 340B Drug Pricing Program and a Medicaid rebate in order to protect drug manufacturers from paying a Medicaid rebate on drugs that are already subject to a Federal discount. This "duplicate discount" prohibition in the Medicaid statute only applies to drugs purchased through the 340B Drug Pricing Program and does not apply to drugs carved out for Medicaid patients and billed to the Medicaid program.

In a recent OIG report, "State Medicaid Policies and Oversight Activities Related to 340B–Purchased Drugs", OEI–05–00321, the OIG reported that many State Medicaid agencies have written policies that direct covered entities to bill at cost for the ingredient cost of 340B purchased drugs or relied on HRSA's 1993 guidance directing covered entities to bill States at AAC (although that guidance is no longer in effect and was superseded by subsequent HRSA guidance directing covered entities to refer to States' policies). We believe that paying 340B providers at cost for these 340B drugs would meet the AAC requirements but seek further comments on what other methodologies would meet the AAC requirements.

IHS, tribal and urban Indian organization pharmacies may purchase drugs through the FSS or the 340B program and are oftentimes paid the Medicaid reimbursement rates established in State plans. In turn, States are reimbursed at 100 percent Federal medical assistance percentage for services provided in IHS and tribal pharmacies. While we have considered alternatives for payment methodologies for IHS, tribal and urban Indian pharmacies, we are proposing no specific methodologies and invite public comment on Medicaid payment levels for these facilities. In addition, pursuant to E.O. 13175 and the HHS Tribal Consultation Policy (December 2010), the CMS will consult with Tribal officials prior to the formal promulgation of this regulation.

We propose that States that do not have specific methodologies develop such methodologies for these providers consistent with our proposed shift from EAC to AAC. In addition, we propose to add a new requirement at § 447.518(a) that the State plan must describe the agency's payment methodology for drugs dispensed by a covered entity participating in the 340B Drug Pricing Program or by a contract pharmacy under contract with a participating covered entity.

In addition, States would be required to submit a SPA through the formal review process, as well as comply with all Federal requirements including consultation with tribal governments and IHS, tribal and urban Indian programs pursuant to section 5006 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), when submitting a request to change their professional dispensing fee. As is true for the drug ingredient reimbursement, we do not intend to mandate a specific formula or methodology which the States must use to determine their dispensing fee, however, as is consistent with current policy, States would still be required to substantiate how their dispensing fee reimbursement to pharmacy providers reasonably reflects the cost of dispensing a drug and will ensure access for these drugs to Medicaid beneficiaries. Where the professional dispensing fee might differ because of unique circumstances for 340B covered entities or IHS and tribal pharmacies, the State should look at these circumstances to determine if a different professional dispensing fee is warranted for these entities. One component of the reimbursement formula should not be revised without appropriately evaluating the other part.

With the proposed change in the definition of "State" to include the territories, we acknowledge that these same requirements could ultimately be applicable to the territories. Since the territories that participate in the

Medicaid Program are already required to submit changes to their State Plans through the State Plan Amendment process, we are proposing that the requirements discussed in this section would be effective for the territories in the same manner in which they would be effective for the 50 States and the District of Columbia.

N. Optional Coverage of Investigational Drugs and Other Drugs Not Subject To Rebate (§ 447.522)

Investigational drugs, also referred to as experimental drugs, do not fall within the definition of covered outpatient drugs set forth in section 1927(k) of the Act; therefore, these drugs are not subject to rebate. However, Medicaid coverage may be provided under section 1905(a)(12) of the Act at the State's option, and FFP is available to the extent it is consistent with section 1903(i) of the Act and § 440.120.

There are a number of other items that may also be covered as prescribed drugs or products under section 1905(a)(12) of the Act, such as whole blood products.

We propose to add § 447.522 to clarify that States providing coverage of investigational drugs may only pay for and receive FFP for these drugs when they are billed for in accordance with the FDA final rules 21 CFR Part 312 and 316, as amended by the final rules published in the August 13, 2009 **Federal Register** ("Charging for Investigational Drugs Under and Investigational New Drug Application" (74 FR 40872) and "Expanded Access to Investigational Drugs for Treatment Use" (74 FR 40900)). These regulations clarify the circumstances under which charging for an investigational drug in a clinical trial is appropriate, set forth criteria for charging for an investigational drug for the different types of expanded access for treatment, and clarify what costs can be recovered.

We are also adding a provision to allow for the coverage of other non-covered outpatient drugs.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICR's Regarding Medicaid Drug Rebates (§ 447.509)

As discussed earlier in the preamble, section 2501(c) of the Affordable Care Act amended section 1903(m) of the Act by specifying new conditions for MCO contracts, including that covered outpatient drugs dispensed to individuals eligible for medical assistance under Title XIX of the Act who are enrolled with a Medicaid MCO shall be subject to the same rebate required by the rebate agreement authorized under section 1927 of the Act. Proposed § 447.509(b) adds requirements for States to collect necessary drug utilization data from Medicaid MCOs in order to include MCO data in the quarterly rebate requests.

We estimate that these requirements would affect the 51 State Medicaid Programs, as well as the territories. The burden associated with the inclusion of Medicaid MCOs in the Drug Rebate Program is the time and effort it would take for the State Medicaid Program to gather the drug utilization information from the Medicaid MCOs and the subsequent inclusion of said data in the State's quarterly rebate request to manufacturers. Our current reporting hour burden, specific to the invoice and State utilization data reporting within the MDR Program, for the current State Medicaid Programs is 2,346 hours per quarter or 9,384 hours annually, at a total estimated cost of $302,165.

As referenced in § 447.509(b) and § 447.511, we believe the collection of drug utilization data from MCOs and the subsequent inclusion of said data in the State's quarterly rebate request to the manufacturers will add a total 678 hours per quarter or 2,712 hours annually to the current reporting burden for the States (which include the 50 States, District of Columbia, and the territories). Therefore, the total new reporting burden, as a result of this proposed rule requesting additional requirements to collect drug utilization data from MCOs, will be 2,712 hours annually at a total estimated cost of $98,744.

The aforementioned burden estimates will be submitted for OMB review and approval as a revision to the information collection request currently approved under OMB control number 0938–0582.

Proposed § 447.509(c) would also require States to remit to the Federal government the amount of the savings resulting from the increases in the rebate percentages. The reporting process is similar to the current reporting process for drug expenditures and rebates onto the CMS–64 Form. In addition to reporting onto the CMS–64 Form the quarterly amount for prescribed drug expenditures, Federal rebates, and rebates under State side bar agreements, States will report the total quarterly rebate offset amount that they are remitting to the Federal government for the fee-for-service rebates they currently receive from drug manufacturers and for the MCO rebates they will receive from drug manufacturers. The information collection requirements and burden associated with CMS–64 are already approved by OMB through April 30, 2014, and have been assigned OMB control number 0938–0067. This proposed rule does not impose any new or revised burden or reporting or recordkeeping requirements concerning CMS–64.

B. ICR's Regarding Requirements for Manufacturers (§ 447.510)

Manufacturers must report, electronically, product and quarterly pricing information to CMS not later than 30 days after the end of the rebate period. Monthly pricing and units are due no later than 30 days after the end of the month. In addition, customary prompt pay discounts and nominal prices must be reported quarterly. The proposed rule would significantly revise the definitions of AMP and best price and, therefore, would require the manufacturers to reconfigure their pricing systems to correctly calculate AMP and best price. In addition, manufacturers must submit the total number of units that are used to calculate the monthly AMP. Therefore, the burden associated with these new requirements is the time and effort it would take for a drug manufacturer to reconfigure its pricing systems to correctly calculate AMP and best price before it can submit the required data to CMS. We estimate that these requirements would affect the approximately 600 drug manufacturers in the Medicaid Rebate Program. We believe the changes to the AMP and best price definitions will require 240 hours

per manufacturer, for a one-time total of 144,000 burden hours with a one-time total estimated burden cost of $8,640,000. Once the pricing systems have been reconfigured, there should be no additional burden in time or effort than that which already exists.

Manufacturers will be required to submit the FDA application number issued by FDA when the product is approved. If the product does not currently have an FDA application number, the manufacturer must submit evidence demonstrating that the product is otherwise a covered outpatient drug. CMS shall refer to this evidence of demonstration as covered outpatient drug status, or COD status.

This information should not be difficult for the manufacturer to determine since the manufacturer should already know the FDA application number of the product when it was approved by FDA, or the reason it qualifies as a covered outpatient drug, if there is no application number.

We estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the reporting of the FDA application number or the COD status is the time and the effort it would take for each drug manufacturer to retrieve this information from their records and submit it to CMS. Therefore, we believe that the new requirements to report the FDA application number and the COD status will require a one-time total of 3,000 hours at a one-time total estimated burden cost of $180,000.

Manufacturers will also be required to identify drugs that are approved by the FDA exclusively for pediatric indications. These drugs will be referred by CMS as "Exclusively Pediatric" drugs. This information should not be difficult for manufacturers to determine and therefore would not add any significant hourly burden since the exclusively for pediatric indications will be provided by the FDA upon approval of these drugs.

Additionally, manufacturers will need to consider certain requirements when it comes to the calculation of their AMP for inhalation, infusion, instilled, implanted, and injectable drugs (5i), when not generally dispensed through retail community pharmacies. Using the methodology proposed earlier in this rule, a manufacturer would be required to identify and determine the AMP of these drugs. It is our estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the initial reporting of the 5i drugs is the time and the effort it would take for each drug manufacturer to identify these drugs and then to determine which of the 5i drugs are not generally dispensed through a retail community pharmacy by using the methodology proposed earlier in this rule. However, it is our understanding that each drug manufacturer should have some knowledge as to which drug is a 5i based on the approval information the manufacturer received from the FDA as well as the FDA Route of Administration list that CMS has identified. Once the manufacturer has established its initial list of 5i drugs, it would then be required on both a monthly, as well as quarterly basis, to determine which of those drugs are not generally dispensed through a retail community pharmacy. Therefore, we believe that the new reporting requirements will require a one-time total of 1,500 burden hours for manufacturers to identify the 5i drugs at a one-time total estimated burden cost of $90,000. In addition, on both a monthly and quarterly basis (12 months, plus 4 quarters, for a total of 16 times per year) the manufacturer will be required to determine whether the percentage of sales for the 5i drugs has met the threshold to be considered not generally dispensed through a retail community pharmacy. Specifically, we estimate that it will add 20 hours per response with 16 responses per year for each manufacturer to identify which 5i drugs are not generally dispensed through a retail community pharmacy. This equates to a total estimate of 320 additional hours annually per manufacturer. The total annual burden hours for the 600 drug manufacturers participating in the Medicaid Rebate Program is estimated to be 192,000 hours with a total cost of $11,520,000.

Furthermore, manufacturers participating in the rebate program that have reformulated drugs are now required to calculate an alternative rebate calculation for certain drugs. In order to calculate the alternative rebate calculation for a line extension drug of a brand name in an oral solid dosage form, the line extension drug and the initial brand name listed drug need to be identified. Although CMS will be identifying both the initial brand name listed drug and the line extension drug for the initial three quarters for manufacturers, they will be responsible for identifying the initial brand name listed drug and the line extension drug after the initial three quarters. Manufacturers are responsible for calculating the unit rebate amount for the line extension drug.

We estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the reporting of the initial brand name listed drug and the line extension drug is the time and the effort it would take for each drug manufacturer to identify these drugs. However, it is our understanding that each drug manufacturer should have some knowledge on which drug is the line extension based on the approval information that the manufacturer received from the FDA as well as the Chemical Type that CMS has identified as a line extension drug and the initial brand name listed drug. Therefore, we believe that the new reporting requirements to identify the initial brand name listed drug and the line extension drug would add 20 additional hours per quarter, per manufacturer; or 48,000 total hours annually to the drug manufacturers at a total estimated cost of $2,880,000.

Finally, a manufacturer is required to retain records for 10 years from the date the manufacturer reports data to CMS for that rebate period. While this requirement is subject to the PRA, we believe this is a usual and customary business practice as defined in 5 CFR 1320.3(b)(2) and, therefore, the associated burden is exempt from the PRA.

The aforementioned burden estimates will be submitted for OMB review and approval as a revision to the information collection request currently approved under OMB control number 0938–0578.

C. ICR's Regarding Requirements for States (§ 447.511)

The definition of the term "States" would be revised to include the territories: The Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, in addition to the 50 States and the District of Columbia. The territories will be able to receive manufacturer rebates through the MDR program in the same manner that the 50 States and the District of Columbia are currently receiving rebates.

In order for territories to be able to begin collecting rebates from the manufacturers, the territories will be required to come into compliance with the MDR program because the systems that the territories currently have are not setup for the MDR program. As a result, these territories will likely have to utilize contractors in order to ensure that their systems are in place to begin to collect rebates from manufacturers.

We are unsure what the time, effort and cost would be for this compliance process to be completed and seek comments specific to this issue.

States will have to report the total MCO rebates they receive from manufacturers onto the MBES CMS–64 Form and submit this data to CMS on a quarterly basis. The information collection requirements and burden associated with CMS–64 are already approved by OMB through April 30, 2014, and have been assigned OMB control number 0938–0067. This proposed rule does not impose any new or revised burden or reporting or recordkeeping requirements concerning CMS–64.

TABLE 5—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§447.509(b), §447.511	*0938–0582	56	224	12.1	2,712	36.41	98,744	0	98,744
§447.510	*0938–0578	600	600	240	144,000	60	8,640,000	0	8,640,000
§447.510	*0938–0578	600	600	5	3,000	60	180,000	0	180,000
§447.510	*0938–0578	600	600	2.5	1,500	60	90,000	0	90,000
§447.510	*0938–0578	600	9600	20	192,000	60	11,520,000	0	11,520,000
§447.510	*0938–0578	600	2400	20	48,000	60	2,880,000	0	2,880,000
Total		3,056	14,024		391,212		23,408,744		23,408,744

*The data contained in the table reflects the burden associated with the proposed revisions to the information collection requests approved under the OMB control numbers listed. The table does not display the currently approved burden for the listed OMB control numbers.

We have submitted a copy of this proposed rule to the OMB for its review of information collection and recordkeeping. These requirements are not effective until they have been approved by the OMB.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS–2345–P] Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an "economically" significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

We solicit comment on the entire Economic Analyses section.

2. Statement of Need

This proposed rule would implement changes to section 1927 of the Act as set forth in section 221 of Division F, Title II, of the Omnibus Appropriations Act, 2009 (Pub. L. 111–8, enacted on March 11, 2009). This includes changes to, (1) section 1927 of the Act as set forth in sections 2501, 2503, and 3301(d)(2) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, enacted on March 23, 2010), (2) section 1927 of the Act as set forth in sections 1101(c) and 1206 of the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152, enacted on March 30, 2010), and (3) section 1927 of the Act as set forth in section 202 of the Education Jobs and Medicaid Funding Act (Pub. L. 111–226, enacted on August 10, 2010). It also proposes to codify other requirements in section 1927 of the Act pertaining to the Medicaid drug rebate program and revise certain regulatory provisions presently codified at 42 CFR part 447, subpart I and make other changes.

3. Overall Impacts

Overall, we estimate this rule would save approximately $17.7 billion for Federal Fiscal Years (FFYs) 2010 through 2014, reflecting $13.7 billion in Federal savings and $4.0 billion in State savings, as shown in the Table 6. These impact estimates represent the increased percentages of rebates on generic and brand name drugs, the treatment of new formulations, the change in the maximum rebate amounts, the extension of rebate collection for Medicaid managed care organizations, and provides for adequate pharmacy reimbursement. Lastly, we estimate costs to MCOs, drug manufacturers, and States in the amount of $81.4 million for FFYs 2010 through 2014 which includes administrative and infrastructure expenses necessary to implement the required systems changes.

[7] Except as noted below, savings estimates were developed by the Office of the Actuary (OACT) and the Center for Medicaid, CHIP and Survey & Certification (CMCS) at CMS and are consistent with the President's FY 2012 budget baseline.

(* The estimates for section 2503 were developed by CMS. An alternative methodology discussed below produces a 5-year cost to States and Federal government of $1.7 billion explained in the alternatives considered section of the Regulatory Impact Analysis).)

Continued

TABLE 6—STATE AND FEDERAL SAVINGS (−) OR COSTS (+) (FFYS 2010–2014)
[In $millions][7]

Affordable Care Act section and provision		2010	2011	2012	2013	2014	Total 2010–2014
Section 2501(a)(1)—Increase minimum rebate percentages for brand name drugs.	Federal	−$350	−$730	−$765	−$810	−$865	−$3,520
	State	0	0	0	0	0	0
Section 2501(a)(2)—Recapture of total savings	Federal	Included with affected provisions					
	State						
Section 2501(b)—Increase rebate percentages for generic drugs.	Federal	−30	−50	−55	−55	−65	−255
	State	0	0	−0	0	0	0
Section 2501(c)—Extension of collection of rebates for MCOs.	Federal	−580	−720	−720	−770	−820	−3,610
	State	−280	−490	−560	−580	−620	−2,530
Section 2501(d)—Rebates new formulation drugs	Federal	−160	−345	−360	−380	−400	−1,645
	State	0	0	0	0	0	0
Section 2501(e)—Maximum rebate amount	Federal	30	40	40	40	50	200
	State	20	30	30	30	30	140
Section 2503—Providing adequate pharmacy*	Federal	0	−351	−702	−702	−702	−2,457
	State	0	−234	−468	−468	−468	−1,638
Interactions**	Federal	−310	−420	−440	−510	−700	−2,380
	State	0	0	0	0	−5	−5
Total Impact	Federal	−1,400	−2,576	−3,002	−3,187	−3,502	−13,667
	State	−260	−694	−998	−1,018	−1,063	−4,033
Total Federal & State Impacts		−1,660	−3,270	−4,000	−4,205	−4,565	−17,700

TABLE 7—COSTS TO MCOS, DRUG MANUFACTURERS, AND STATES
[FFYs 2010–2014]

Provision(s)	Regulation section(s)	(In $millions)					Total
		2010	2011	2012	2013	2014	(FFYs 2010–2014)
Drug Rebates for Medicaid MCOs	§447.509(b), §447.511	$0.1	$0.1	$0.1	$0.1	$0.1	$0.49
Requirements for manufacturers	§447.510	23.3	14.4	14.4	14.4	14.4	80.91
Total Costs		23.4	14.5	14.5	14.5	14.5	81.4

4. Detailed Economic Analysis

All savings estimates provided were developed by the Office of the Actuary (OACT) and the Center for Medicaid, CHIP and Survey & Certification (CMCS) at CMS. We note that the Congressional Budget Office (CBO), in its estimates of the budgetary effects of these provisions of the Affordable Care Act, reached similar aggregate estimates with a $600 million difference between CMS and CBO total estimates. The report can be seen at the following link (*http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf*). CBO reached an estimated savings of $13.1 billion in Federal outlay reduction for FFY 2010–2014 compared to CMS' estimates of $13.7 billion for that same time period.[8] Savings estimates for sections 2501 and 2503 of the Affordable Care Act reflect increased rebate percentages for generic and brand name drugs, treatment of new formulations, revised FULs, and extended collection of rebates to MCOs. As well as a cost estimate for provision of section 2501(e) of Affordable Care Act for maximum rebate amount. The following analysis describes the methodology used to reflect each provision's savings estimates.

The estimates for section 2501(a)(1) of the Affordable Care Act were derived from baseline Medicaid prescription drug rebates developed for the mid-session review (MSR) of the FY 2010 budget. Data from the MDR system was used to estimate the share of rebates attributable to single source and innovator multiple source drugs. Using this data, we developed a model to estimate the effect of raising the minimum rebate by fitting a distribution to data on brand drug rebates as a percent of AMP with and without the 15.1 percent minimum. The distribution was then used to calculate the mean rebate percentage taking into account the new minimums specified in section 2501(a) of the Affordable Care Act. These percentages were applied to baseline brand drug rebates to estimate potential savings from the provision. A behavioral offset of 40 percent was applied to the potential savings to account for actions on the part of manufacturers to minimize the impact of the higher rebate payments (for example, by raising prices).

The estimate for section 2501(a)(2) of the Affordable Care Act represents the State share of savings projected for subsections (a)(1),(b), and (d) of section 2501 and is included in the Federal savings of those subsections.

The impact of section 2501(b) of the Affordable Care Act was estimated using MDR data to estimate the share of baseline Medicaid drug rebates attributable to non-innovator, multiple source drugs. Increasing the rebate from 11 percent to 13 percent of AMP results in additional rebates of 2 percent of AMP, or about 18 percent (2/11) of projected generic drug rebates.

For section 2501(c) of the Affordable Care Act, current projections of Medicaid prescription drug spending and managed care premiums were developed as part of the MSR 2010 Medicaid baseline. The estimated impact represents two different effects of this section. First, current prescription drug spending by Medicaid

(** These are interactions among drug provisions and the interaction of drug provisions with Medicaid expansion.)

[8] *http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf.*

managed care plans would receive additional rebates. Estimates for (1) the portion of managed care plan expenditures going to rebates and (2) the level of additional rebates that could be obtained by the managed care plans were developed to calculate this impact.

Second, it is anticipated that some fee-for-service prescription drug spending that is currently carved out of Medicaid managed care plans would be included in future managed care contracts. To develop this estimate, estimates were made for (1) the increased efficiency of managed care plans in managing prescription drug use, and (2) the increased administrative costs by including additional expenditures under managed care plans. It was also assumed that 10 percent of current fee-for-service drug spending would eventually shift to Medicaid managed care plans.

About 75 percent of the savings to the Federal government from this section are estimated to come from the impact of additional rebates for managed care plan expenditures on prescription drugs, and about 25 percent are estimates to come from the impact of moving fee-for-service prescription drug spending into managed care plans.

The impact for section 2501(d) of the Affordable Care Act utilized MDR data and focused on new formulations that are extended-release forms of the initial brand name listed drug. The analysis concluded that by calculating the additional rebate, based on the initial brand name listed drug, Medicaid rebates would increase by about 5 percent. A behavioral offset of 15 percent was applied to these potential savings.

The estimates for section 2501(e) of the Affordable Act were derived from an analysis of MDR data for single source and innovator multiple source drugs for which the unit rebate amount exceeds the AMP. The amount of rebates in excess of AMP was found to account for approximately one percent of total Medicaid rebates.

The estimate for FULs under section 2503 was developed by calculating the FUL based on weighted AMP times 175 percent, including (I) innovator and (N) non-innovator drugs, for the purpose of savings and providing adequate reimbursement to pharmacy providers.

a. Anticipated Effects on Drug Manufacturers

As previously indicated in the Collection of Information there are approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate program. The rule would require all drug manufacturers to provide an increased rebate percentage for generic and brand name drugs.

The burden associated with the drug program is for labelers to gather and report existing sales and product information on an additional monthly basis and an expanded quarterly basis. As mentioned previously there are approximately 600 drug manufacturers who will have to provide reporting drug information to CMS. We believe each manufacturer will spend a one-time annual burden of approximately 144,000 total hours in complying with these requirements. The estimated one-time cost to labelers is $8.6 million. This information is required for the new base AMP and the new best price. This is based on the Bureau of Labor Statistics (BLS) average rate of $60.00 an hour for a computer systems analyst.

Manufacturers also will be required to submit the FDA application number issued by FDA when the product is approved. If the product does not currently have an FDA application number, the manufacturer must provide a demonstration that product is a covered outpatient drug, or a COD status. We estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the reporting of the FDA application number or the COD status is the time and the effort it would take for each drug manufacturer to retrieve this information from their records and submit it to CMS. Therefore, we believe that the new requirements to report the FDA application number or the COD status will require a total one-time burden of 3,000 hours at an estimated cost of $180,000. This is based on the BLS average rate of $60.00 an hour for a computer systems analyst.

In addition, we believe that it will take time for manufacturers to identify the drugs that fall into 5i drugs category. We estimate they will spend a one-time total of 1,500 burden hours to identify these drugs. This translates to a one-time cost for manufacturers to identify the 5i drugs of $90,000, utilizing the average BLS wage rate of $60 an hour for this function. Furthermore, we believe that it will require all manufacturers to spend 192,000 total hours annually in identifying which drugs fall into the 5i category. The estimated cost to the labelers for this addition is $11.5 million. This is also based on the average BLS wage rate of $60 an hour for this function. More information on manufacturer requirements can be found in § 447.510 of this proposed rule.

Lastly, we believe that the initial identification of the initial brand name listed drug and the line extension would also add an additional 48,000 annual hours to identify which drugs with the extension qualify. The estimated additional cost to labelers for this addition is also $2.9 million. This figure is also based on the average BLS wage rate of $60 an hour for this function. Additional information can be found in section § 447.510 of this proposed rule.

b. Anticipated Effects on Retail Community Pharmacies

Retail community pharmacies would be affected by this regulation, as the law will result in FULs that are closer to the acquisition cost of the drug. In a 2009 OIG report titled "A Comparison of Medicaid Federal Upper Limit Amounts to Acquisition Costs, Medicare Payment Amounts, and Retail Prices," the OIG found that for the fourth quarter of FY 2007 the pre-DRA FUL reimbursement was more than double the average pharmacy acquisition cost for 46 of the 50 highest- expenditure FUL drugs. The Affordable Care Act FULs would generally reduce those limits in comparison to the pre-DRA highly inflated FULs and, thereby, reduce Medicaid payment for drugs subject to the limits. However, we note that since States had the option to reimburse at their SMAC, instead of the pre-DRA FUL, the actual reimbursement to the pharmacies under the Affordable Care Act FUL may be more compared to that SMAC reimbursement. An example of this is exemplified in comparing the pre-DRA FUL, the Affordable Care Act FUL and Indiana's SMAC, as explained the preamble of § 447.514 of this proposed rule.

However, other than the comparison chart provided in § 447.514 of this proposed rule, we have not analyzed how each State's MAC program would impact the total savings under the new Affordable Care Act FUL methodology. Therefore, we invite public comments on this impact. The Federal savings in section 2503 of the Affordable Care Act reflect this change in reimbursement for retail community pharmacies. Although there are savings to the Medicaid program largely realized because of lower payment to pharmacies, pharmacies may receive a higher reimbursement under the Affordable Care Act FUL than they would when compared to what States currently reimburse pharmacies.

c. Anticipated Effects on State Medicaid Programs

States share in the savings from this rule. As noted in the Table 6, we

estimate a 5-year State savings of over $4.0 billion. We also note States would be impacted by the provisions of this regulation that offset the States' share of the increased rebate amounts under the Affordable Care Act. State administrative costs associated with this regulation are minor; as States currently pay based on a FUL, have already determined their drug reimbursement rates, and currently collect claims information on physician administered drugs.

The States will have added reporting data for the MCOs to CMS and we believe that this will require a total of 2,712 hours annually costing the States $98,744.

Also, as a result of the increased rebate amounts under the national rebate agreement, manufacturers may reduce rebates they pay to States through supplemental rebate agreements. While this potential loss of supplemental rebates is not a direct consequence of this proposed rule, we recognize that this may occur.

The interactions of the drug provisions with the Medicaid expansion in the Affordable Care Act will provide States a savings of $5 million in FFY 2014. More information can be found in § 447.509(c) and § 447.511 of this proposed rule.

d. Anticipated Effects on U.S. Territories

The definition of the term "States" would be revised to include the territories: The Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, in addition to the 50 States and the District of Columbia. The territories will be able to receive manufacturer rebates through the MDR program in the same manner that the 50 States and the District of Columbia are currently receiving rebates.

In order for territories to be able to begin collecting rebates from the manufacturers, the territories will be required to come into compliance with the MDR program because the systems that the territories currently have are not setup for the MDR program. As a result, these territories will likely have to utilize contractors in order to ensure that their systems are in place to begin to collect rebates from manufacturers. We do not have cost estimates for this compliance process to be completed and solicit comment specific to this issue.

5. Alternatives Considered

We considered a number of different policies and approaches during the development of this proposed rule.

As mentioned in the Determination of AMP § 447.504, the goal of the Affordable Care Act is to capture the AMP for those drugs that would be difficult for manufacturers to calculate an AMP based on only retail community pharmacy sales. Therefore, to eliminate any problems that may result from a manufacturer not able to determine an AMP for a particular drug, Congress amended the Affordable Care Act to include inhalation, infusion, instilled, implanted, or injectable drugs that are not generally dispensed through retail community pharmacies. We considered whether we need to define and determine which drugs constitute the five aforementioned. Also, we looked at Medicare Part B drugs and considered using their list to define these drugs. Though, when speaking with our counterparts in Medicare Part B, the ASP NDC–HCPCS covered drugs that are usually not self administered were not all inclusive. In addition to using the Medicare Part B list, we also considered whether CMS or manufacturers would be responsible for defining which drugs would fall into this category. Additionally, we considered using the FDAs dosage forms and route of administrations to assist manufacturers in determining which drugs meet this requirement.

We propose to use a multistep process to identify if the drug is not generally dispensed. To recap, first manufacturers would identify which drugs would fall within the parameters of the five aforementioned drugs. Then, they would need to determine if the drug is "not generally dispensed" through a retail community pharmacy. (See § 447.504 to learn more about the alternatives considered in developing AMP policy.)

With regard to the offset of the increased rebate percentages, we did consider offsetting the non-Federal share of the entire difference between the minimum rebate percentages in effect on December 31, 2009 and the new minimum rebate percentages in effect under Affordable Care Act, regardless of whether States received a rebate amount based on the difference between AMP and best price. However, after careful consideration of the provision in 2501 of the Affordable Care Act, we propose to calculate the offset amount to reflect rebates based on the difference between AMP and best price.

We also considered a different interpretation when calculating the offset for line extension drugs. However, we believe that the new alternative rebate calculation is more aligned than the statute.

We also considered determining whether there would be a cost or savings in implementing the Affordable Care Act FUL by comparing simulations of the DRA FUL and new Affordable Care Act FUL, using price, utilization, and reimbursement data from the MDR system combined with generic group codes from First Data Bank. The difference in savings from these simulations (expressed as a percent of total Medicaid drug spending) was applied to projected Medicaid prescription drug spending developed for the mid-session review of the FY 2010 Budget, resulting in a five-year Federal and State cost of $1.7 billion for the Affordable Care Act FULs compared to the DRA FULs. However, this alternative does not take into account a State's ability to choose to reimburse at the SMACs, which may be lower than the FUL for a drug. As a result, this alternative/methodology yields a cost to the States and Federal government, when in actuality it should reflect a savings as many States have implemented their own SMAC and reimburse below the FUL. In addition, the DRA FUL was never implemented and therefore this alternative is based on unpublished FULs and not representative of actual reimbursement.

We solicit comment on the Alternatives Considered section.

6. Accounting Statement and Table

As required by OMB's Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the Table 8 we have prepared an accounting statement showing the classification of the transfers and costs associated with the provisions of this proposed rule. Table 9 provides our best estimate of the decreases in Medicaid payments and increase in drug rebates under sections 2501(a), 2501(b), 2501(c), 2501(d), 2501(e), and 2503 of the Affordable Care Act. All transfers to the Federal and State Medicaid program are from retail pharmacies and drug manufacturers. Lastly, we present the costs to MCOs, Drug Manufacturers, and States.

TABLE 8—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS, FROM FFYS 2010 TO 2014

[In $millions]

Category	TRANSFERS			
Annualized Monetized Transfers	Year Dollar	Discount Rate		Period Covered
	2011	7%	3%	FFYs 2010–2014
	Primary Estimate	−$2,667.5	−$2,704.8	
From/To	Reduction in transfers from the Federal Government to State Governments.			
Category	TRANSFERS			
Annualized Monetized Transfers	Year Dollar	Discount Rate		Period Covered
	2011	7%	3%	FFYs 2010–2014
	Primary Estimate	−$780.0	−$795.1	
From/To	Reduction in transfers from the State Governments to Retail Pharmacies and increased transfers from Drug Manufacturers to State Governments.			
Category	COSTS			
Annualized Monetized Transfers	Year Dollar	Units Discount Rate		Period Covered
	2011	7%	3%	FFYs 2010–2014
	Primary Estimate	$16.5	$16.4	
	Costs to MCOs, Drug Manufacturers, and States.			

7. Conclusion

We estimate savings from this regulation of $17.7 billion over 5 years, $13.7 billion to the Federal government and $4.0 billion to the States. Most of these savings result from the increased rebate percentages on brand name drugs and the offsets of the total savings of the increased rebate percentage, treatment of new formulations, and from the collection of rebates from enrollees of MCOs. Lastly, we estimate costs to MCOs, drug manufacturers, and States of $81.4 million for FFYs 2010 through 2014.

While the effects of this regulation are substantial, they are a result of changes in the law.

B. Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, three types of small businesses are potentially impacted by this proposed rule. These include small retail community pharmacies, small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, and small Medicaid managed care organizations (MCOs). More detailed analysis on the impact of these entities is provided in the Detailed Economic Analysis section (V.A.4) above. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration's (SBA) definition of a small business (having revenues of less than $7.0 million to $34.5 million in any one year).

TABLE 9—IMPACT ON SMALL ENTITIES

Small entity type	Number of entities	Impact (FFYs 2010–2014)
Pharmaceutical Manufacturers in Medicaid Drug Rebate Program	600	Decrease in revenue of $5.4 billion as a result of higher rebates over 5 years.
Small Retail Community Pharmacies	17,069	Minimal impact.
Small Rural Hospitals	700	Minimal impact.
Small (HMOs/MCOs) Health Maintenance Organizations/Managed care organizations	*118	Decrease in revenue of $6.1 billion over 5 years.

(* Figure may reflect overestimation relative to overall MCOs.)

For purposes of the RFA, most of the retail pharmacies are considered small businesses according to the SBA's size standards with total revenues of $25.5 million or less in any 1 year (*http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13*). The latest 2007 SBA estimates that there are approximately 17,069 small pharmacies. These pharmacies would be affected by this regulation as the law will result in lower FULs for most drugs subject to the payment limits, thus reducing Medicaid payments to pharmacies for generic drugs. The revision to the FULs would generally reduce those limits and, thereby reduce Medicaid payments for drugs that are subject to the payment limits. The savings for section 2503 of the Affordable Care Act reflect this statutory change. Beginning September 2011, the publication of AWP by First Databank would in all likelihood cease; therefore, CMS proposes to replace the term "estimated acquisition cost" with Actual Acquisition Cost (AAC) and require States to begin paying pharmacy providers based on the AAC of the drug. Additionally States will reimburse providers with a comparable dispensing fee as mentioned in § 447.502 of this proposed rule. There will be a savings for States and the Federal government for reimbursing pharmacists at AAC because of the highly inflated prices that the Medicaid programs are currently reimbursing providers.

According to the SBA size standards, drug manufacturers are considered small businesses if they have fewer than 750 employees (*http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13*). Approximately 600 drug manufacturers currently participate in the Medicaid Drug Rebate Program. We believe most manufacturers are small businesses. We anticipate this rule would have an impact on small drug manufacturers. We believe there will be an impact on these entities and solicit comments on this analysis.

The rule would require all drug manufacturers participating in the Medicaid Drug Rebate program to increase the rebate percentages that they are currently paying. Manufacturers are required by the Affordable Care Act to pay the increased percentages. The savings for sections 2501(a)(1), 2501(b) and 2501(d) reflect this statutory change.

According to the SBA's size standards, an HMO, of which we have included MCOs, is considered a small business if it has revenues of $10 million or less in any one year (*http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13*). The SBA estimates that there are approximately 118 small HMO/MCO Medical centers that meet this threshold. Because of limited data available, we are unable to quantify how many MCOs fall within the HMO standard and meet the $10 million threshold. We do contend that only a small portion of the small MCOs meet this standard. We request any information that may help us better estimate the portion of MCOs that meet the SBA standard. The small Medicaid MCOs may be affected by this rule if manufacturers reduce rebate payments to them to any extent that these rebates are paid to the States but these costs would likely be mitigated because it is likely that the MCOs rates would be adjusted.

Therefore, the Secretary has determined that this proposed rule would have a significant economic impact on a substantial number of small entities. We offer an analysis of the alternatives considered in section V.A.5 of this proposed rule. The analysis above, together with the remainder of this preamble, constitutes the initial regulatory flexibility analysis. We solicit comment on the RFA analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. There are approximately 700 small rural hospitals that meet this definition. We do not expect this rule to have a significant impact on small rural hospitals although States are now required to furnish rebates from MCOs including NDCs for physician administered drugs. The national cost of this provision would be estimated at $580 million for FY 2010. However, the impact on these entities would be minimal because there would be no other requirement except for providing NDC numbers for physician administered drugs. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals. At this time, we are unable to specifically estimate quantitative effects on small retail pharmacies, particularly those in low income areas where there are high concentrations of Medicaid beneficiaries. We request any information that may help us better assess those effects before we make final decisions.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. We expect this proposed rule would impose additional costs to manufacturers, whereas it would likely increase savings for States and the Federal government. A detailed discussion on costs is offered below. We believe the rule would not impose additional costs to States and local governments. This proposed rule will have tribal implications, and in accordance with E.O. 13175 and the HHS Tribal Consultation Policy (December 2010), CMS will consult with Tribal officials prior to the formal promulgation of this regulation.

There would be additional costs for drug manufacturers. This occurs as a result of the increased rebate percentages for generic and brand name drugs, and the treatment of new formulation drugs which for manufacturers, total over $11.2 billion dollars over the next 5 years.

VI. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule does not impose substantial direct requirement costs on State or local governments, preempts State law, or otherwise has Federalism implications.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare &

Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS FOR SERVICES

1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Subpart I is revised to read as follows:

Subpart I—Payment for Drugs

Secs.

Subpart I—Payment for Drugs

§ 447.500 Basis and purpose.

(a) *Basis.* This subpart—

(1) Interprets those provisions of section 1927 of the Act that set forth requirements for drug manufacturers' calculating and reporting average manufacturer prices (AMPs) and best prices and that set upper payment limits for covered outpatient drugs.

(2) Implements section 1903(i)(10) of the Act with regard to the denial of Federal financial participation (FFP) in expenditures for certain physician-administered drugs.

(3) Implements section 1902(a)(54) of the Act with regard to a State plan that provides covered outpatient drugs.

(4) Implements section 1903(m)(2)(A)(xiii) of the Act, in part, and section 1927(b) of the Act with regard to rebates for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled in Medicaid Managed Care Organizations (MCOs).

(5) Implements section 1902(a)(30)(A) of the Act with regard to the efficiency, economy, and quality of care in the context of payments for covered outpatient drugs.

(b) *Purpose.* This subpart specifies certain requirements in the Social Security Act, including changes from the Affordable Care Act and other requirements pertaining to Medicaid payment for drugs.

§ 447.502 Definitions.

For the purpose of this subpart, the following definitions apply:

5i drug means an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy.

Actual acquisition cost (AAC) means the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.

Authorized generic drug means any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand name drug.

Bona fide service fee means a fee paid by a manufacturer to wholesalers or retail community pharmacies; that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. The fee includes, but is not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs).

Brand name drug means a single source or innovator multiple source drug.

Bundled sale means any arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.

(1) The discounts in a bundled sale, including but not limited to those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs sold under the bundled arrangement.

(2) For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs in the bundle.

Clotting factor means a hemophilia clotting factor for which a separate furnishing payment is made under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by the CMS and posted on the CMS Web site.

Consumer Price Index—Urban (CPI–U) means the index of consumer prices developed and updated by the U.S. Department of Labor. It is the CPI for all urban consumers (U.S. average) for the month before the beginning of the calendar quarter for which the rebate is paid.

Covered outpatient drug means of those drugs which are treated as a prescribed drug for the purposes of section 1905(a)(12) of the Act, a drug which may be dispensed only upon a prescription (except as provided in paragraphs (2) and (3) of this definition).

(1) A drug can only be considered a covered outpatient drug if it:

(i) Is approved for safety and effectiveness as a prescription drug by the FDA under section 505 or 507 of the FFDCA where the manufacturer has obtained a NDA and also under section 505(j) of the FFDCA where the manufacturer has obtained an ANDA;

(ii) Was commercially sold in the United States before the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug, and which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the FFDCA) or an action brought by the Secretary under sections 301, 302(a), or 304(a) of FFDCA to enforce section 502(f) or 505(a) of the FFDCA;

(iii) Is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need or is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug or for which the Secretary has not issued a notice for

an opportunity for a hearing under section 505(e) of the FFDCA. This provision specifies a proposed order of the Secretary to withdraw approval of an application for such drug under section 505(e) of the FFDCA because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended or suggested in its labeling;

(iv) Is a biologic product other than a vaccine that may only be dispensed upon a prescription and is licensed under section 351 of the Public Health Service Act (PHSA) and is produced at an establishment licensed under section 351 of the PHSA to produce such product; or

(v) Is insulin certified under section 506 of the FFDCA.

(2) A covered outpatient drug does not include any drug, biologic product, or insulin provided as part of or incident to and in the same setting as, any of the following services (and for which payment is made as part of that service instead of as a direct reimbursement for the drug):

(i) Inpatient Services;

(ii) Hospice Services;

(iii) Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;

(iv) Physician services;

(v) Outpatient hospital services;

(vi) Nursing facility and services provided by an intermediate care facility for the mentally retarded;

(vii) Other laboratory and x-ray services; or

(viii) Renal dialysis.

(3) A covered outpatient drug does not include:

(i) Any drug product, prescription or OTC, for which an NDC number is not required by the FDA;

(ii) Any drug product that is not listed electronically with the FDA;

(iii) Any drug product for which a manufacturer has not submitted to CMS evidence to demonstrate that the drug product satisfies the criteria in paragraph (1) of this definition;

(iv) Any drug product or biological used for a medical indication which is not a medically accepted indication; or

(v) Over-the-counter products that are not drugs.

Customary prompt pay discount means any discount off of the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified timeframe and consistent with customary business practices for payment.

Innovator multiple source drug means a multiple source drug marketed under a new drug application (NDA) approved by the FDA, including an authorized generic drug. It includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a biologic license application (BLA), product license approval (PLA), establishment license approval (ELA) or antibiotic drug approval (ADA). For purposes of the MDR program, an original NDA is equivalent to an NDA filed by the manufacturer for approval under section 505 of the FFDCA for purposes of approval by the FDA for safety and effectiveness.

Lagged price concession means any discount or rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts.

Line extension means a single source or innovator multiple source drug that is in an oral solid dosage form that has been approved by the FDA as a change to the initial brand name listed drug in that it represents a new version of the previously approved listed drug, such as a new ester, a new salt, or other noncovalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication for an already marketed drug.

Manufacturer means any entity that holds the NDC for a covered outpatient drug or biological product and—

(1) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(2) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(3) For authorized generic products, the term "manufacturer" will also include the original holder of the NDA.

(4) For drugs subject to private labeling arrangements, the term "manufacturer" will also include the entity under whose own label or trade name the product will be distributed.

Multiple source drug means, for a rebate period, a covered outpatient drug for which there is at least one other drug product which—

(1) Is rated as therapeutically equivalent as reported in the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" which is available at *http://www.fda.gov* or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A–30, Rockville, MD 20857 or successor publications and Web sites;

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA; and

(3) Is sold or marketed in the United States during the rebate period.

National drug code (NDC) means the numerical code maintained by the FDA that includes the labeler code, product code, and package code. For purposes of this subpart, the NDC is considered to be an 11-digit code, unless otherwise specified in this subpart as being without regard to package size (that is, the 9-digit numerical code).

National rebate agreement means the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his or her designee and a manufacturer to implement section 1927 of the Act.

Nominal price means a price that is less than 10 percent of the AMP in the same quarter for which the AMP is computed.

Noninnovator multiple source drug means—

(1) A multiple source drug that is not an innovator multiple source drug or a single source drug;

(2) A multiple source drug that is marketed under an abbreviated NDA or an abbreviated antibiotic drug application;

(3) A covered outpatient drug that entered the market before 1962 that was not originally marketed under an NDA;

(4) Any drug that has not gone through an FDA approval process, but otherwise meet the definition of covered outpatient drug; or

(5) Any noninnovator drug that is not therapeutically equivalent.

(6) If any of the drug products listed in this definition of a noninnovator multiple source drug subsequently receives a new NDA or ANDA approval from the FDA, the manufacturer must change the reporting of the product's drug category to correlate with the new product application type and furnish the appropriate information.

Oral solid dosage form means capsules, tablets, or similar drugs products intended for oral use as defined in accordance with the FDA regulation at 21 CFR 206.3 that defines solid oral dosage form.

Over-the-counter drug means a drug that is appropriate for use without the supervision of a health care professional such as a physician, and which can be

purchased by a consumer without a prescription.

Pediatric indication means a specifically stated indication for use by the pediatric age group, meaning from birth through 16 years of age, or a subset of this group, as specified in the "Indications and Usage" section of the FDA approved labeling.

Professional dispensing fee means the professional fee which—

(1) Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

Rebate period means a calendar quarter.

Single source drug means a covered outpatient drug that is produced or distributed under an NDA approved by the FDA and has an approved NDA number issued by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a biological license application (BLA), product license approval (PLA), establishment license approval (ELA), or antibiotic drug approval (ADA). For purposes of the MDR program, an original NDA is equivalent to an NDA filed by the manufacturer for approval under section 505 of the FFDCA for purposes of approval by the FDA for safety and effectiveness.

States means the 50 States, the District of Columbia and the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and America Samoa).

United States means the 50 States, the District of Columbia, and the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and America Samoa).

Wholesaler means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

§ 447.504 Determination of Average Manufacturer Price.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Average Manufacturer Price (AMP) means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA)), the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.

Average unit price means a manufacturer's sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

Charitable and not-for profit pharmacies means organizations exempt from taxation as defined by section 501(c)(3) of the Internal Revenue Code of 1986.

Insurers means entities that are responsible for payment to pharmacies for drugs dispensed to their members, and do not take actual possession of these drugs or pass on manufacturer discounts or rebates to pharmacies.

Net sales means quarterly gross sales revenue less cash discounts allowed, except customary prompt pay discounts extended to wholesalers, and all other price reductions (other than rebates under section 1927 of the Act or price reductions specifically excluded by statute or regulation) which reduce the amount received by the manufacturer.

Retail community pharmacy means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, and a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

(b) *Sales, nominal price sales, discounts, rebates, payments, or other transactions included in AMP.* Except for those sales, nominal price sales, rebates, discounts and other financial transactions identified in paragraph (c) of this section, AMP for covered outpatient drugs includes the following sales, nominal price sales and associated discounts, rebates, payments, or other transactions:

(1) Sales to wholesalers for drugs distributed to retail community pharmacies.

(2) Sales to other manufacturers who act as wholesalers for drugs distributed to retail community pharmacies.

(3) Sales, discounts, rebates (other than rebates under section 1927 of the Act or as otherwise specified in regulations), payments, or other financial transactions that are received by, paid by, or passed through to retail community pharmacies.

(4) Sales, discounts, rebates (other than rebates under section 1927 of the Act or as otherwise specified in regulations), payments, or other financial transactions that are received by, paid by, or passed through to entities that conduct business as wholesalers or retail community pharmacies, which includes but is not limited to specialty pharmacies, home infusion pharmacies and home healthcare providers.

(c) *Sales, nominal price sales, rebates, discounts, or other transactions excluded from AMP.* AMP excludes the following sales, nominal sales, rebates, discounts, or other transactions:

(1) Any prices on or after October 1, 1992, to the Indian Health Service (IHS), the Department of Veterans Affairs (DVA), a State home receiving funds under 38 U.S.C. 1741, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA).

(2) Any prices charged under the Federal Supply Schedule (FSS) of the General Services Administration (GSA).

(3) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal government.

(4) Sales outside the United States.

(5) Direct and indirect sales to hospitals.

(6) Sales to health maintenance organizations (HMOs) (including managed care organizations (MCOs)), including HMO or MCO operated pharmacies.

(7) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities.

(8) Sales to mail order pharmacies.

(9) Sales to clinics and outpatient facilities (for example, surgical centers, ambulatory care centers, dialysis centers, and mental health centers).

(10) Sales to government pharmacies (for example, a Federal, State, county, or municipal-owned pharmacy).

(11) Sales to charitable pharmacies.

(12) Sales to not-for-profit pharmacies.

(13) Sales, associated rebates, discounts, or other price concessions paid directly to insurers.

(14) Bona fide service fees paid by manufacturers to wholesalers, retail community pharmacies, or any other entity that conducts business as a wholesaler or a retail community pharmacy, including but not limited to inventory management fees, product stocking allowances, and fees associated with administrative agreements and patient care programs (such as medication compliance programs and patient education programs), including bona fide service fees paid to Group Purchasing Organizations.

(15) Customary prompt pay discounts extended to wholesalers.

(16) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction but only to the extent that such payment covers only those costs.

(17) Associated discounts, rebates, or other price concessions provided under the Medicare Coverage Gap Discount Program under section 1860D–14A of the Act.

(18) Sales to PBMs, including their mail order pharmacy's purchases.

(19) Rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(20) Sales to hospices (inpatient and outpatient).

(21) Sales to prisons.

(22) Direct sales to physicians.

(23) Direct sales to patients.

(24) Free goods, not contingent upon any purchase requirement.

(25) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.

(26) Manufacturer vouchers.

(27) Prices negotiated under Manufacturer-sponsored drug discount card programs.

(28) Goods provided free of charge under Manufacturer-sponsored patient refund/rebate programs.

(29) Goods provided free of charge under Manufacturer copayment assistance programs and patient assistance programs.

(d) *Sales and associated discounts, rebates, payments, or other transactions included in AMP for inhalation, infusion, instilled, implanted, or injectable drugs (5i drugs) not generally dispensed through a retail community pharmacy.* AMP for 5i covered outpatient drugs indentified in accordance with § 447.507 of this subpart shall include sales and associated discounts, rebates, payments or other financial transactions to all entities as specified in paragraph (b) of this section, as well as the following sales and associated discounts, rebates, payments or other transactions:

(1) Sales to physicians.

(2) Sales to pharmacy benefit managers where the PBM is not acting as an insurer, including its mail order pharmacy purchases.

(3) Sales to health maintenance organizations (HMOs), including managed care organizations (MCOs).

(4) Sales, discounts, or rebates paid directly to insurers (except for rebates under section 1927 of the Act and this subpart).

(5) Sales to hospitals.

(6) Sales to clinics and outpatient facilities (for example, surgical centers, ambulatory care centers, dialysis centers, mental health centers).

(7) Sales to mail order pharmacies.

(8) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities.

(9) Sales to hospices.

(10) Sales to other manufacturers who conduct business as a wholesaler or retail community pharmacy.

(e) Further clarification of AMP calculation.

(1) AMP includes cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, chargebacks that can be identified with adequate documentation, incentives, administrative fees, service fees, distribution fees, and any other rebates, discounts or other financial transactions, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to retail community pharmacies.

(2) Quarterly AMP is calculated as a weighted average of monthly AMPs in that quarter.

(3) The manufacturer must adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized, to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the determination of AMP by statute or regulation.

§ 447.505 Determination of best price.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Best price means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under an NDA approved under section 505(c) of the FFDCA), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed.

Provider means a hospital, HMO, including an MCO, or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care.

(b) *Prices included in best price.* Except for those prices identified in paragraph (c) of this section, best price for covered outpatient drugs includes all prices and associated rebates, discounts, or other transactions that adjust prices either directly or indirectly.

(c) *Prices excluded from best price.* Best price excludes the following:

(1) Any prices on or after October 1, 1992, charged to the IHS, the DVA, a State home receiving funds under 38 U.S.C. 1741, the DoD, or the PHS.

(2) Prices to 340B covered entities.

(i) Prices charged under the 340B drug pricing program to a covered entity described in section 1927(a)(5)(B) of the Act; and

(ii) Any inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA.

(3) Any prices charged under the FSS of the GSA.

(4) Any prices provided to a designated State Pharmacy Assistance Program (SPAP).

(5) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal government.

(6) Any prices charged which are negotiated by a prescription drug plan under Part D of title XVIII, by any MA–PD plan under Part C of such title with respect to covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D–22(a)(2) of the Act) for such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A of the Act.

(7) Rebates under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(8) Prices negotiated under manufacturer-sponsored drug discount card programs.

(9) Manufacturer coupons to a consumer redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.

(10) Goods provided free of charge under Manufacturer copayment assistance programs and patient assistance programs.

(11) Goods provided free of charge under Manufacturer-sponsored patient refund or rebate programs.

(12) Manufacturer vouchers.

(13) Free goods, not contingent upon any purchase requirement.

(14) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including, but not limited to, reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction but only to the extent that it only covers these costs.

(15) Nominal prices to certain entities as set forth in § 447.508 of this subpart.

(16) Bona fide service fees paid by manufacturers to wholesalers, retail community pharmacies, or any other entity that conducts business as a wholesaler or a retail community pharmacy, including but not limited to inventory management fees, product stocking allowances, and fees associated with administrative agreements and patient care programs (such as medication compliance programs and patient education programs), including bona fide service fees paid to Group Purchasing Organizations.

(17) PBM rebates, discounts, or other financial transactions except their mail order pharmacy's purchases or where such rebates, discounts, or other financial transactions are designed to adjust prices at the retail or provider level.

(18) Sales outside the United States.

(d) *Further clarification of best price.*

(1) Best price is net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, returns, incentives, promotional fees, administrative fees, service fees, distribution fees, and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price available from the manufacturer.

(2) Best price must be determined on a unit basis without regard to package size, special packaging, labeling or identifiers on the dosage form or product or package.

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer.

§ 447.506 Authorized generic drugs.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Primary manufacturer means a manufacturer that holds the NDA of the authorized generic drug.

Secondary manufacturer of an authorized generic drug means a manufacturer that is authorized by the primary manufacturer to sell the drug but does not hold the NDA.

(b) *Inclusion of authorized generic drugs in AMP by a primary manufacturer.* The primary manufacturer must include in its calculation of AMP its sales of authorized generic drugs that have been sold or licensed to a secondary manufacturer, acting as a wholesaler, or when the primary manufacturer holding the NDA sells directly to a wholesaler.

(c) *Inclusion of authorized generic drugs in best price by a primary manufacturer.* A primary manufacturer holding the NDA must include the best price of an authorized generic drug in its computation of best price for an innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity in the United States, only when such drugs are being sold by the manufacturer holding the NDA.

(d) *Inclusion of authorized generic in AMP and best price by a secondary manufacturer.* The secondary manufacturer of an authorized generic drug must provide a rebate based on its sales of authorized generics, and must calculate AMP and best price, consistent with the requirements specified in § 447.504 and § 447.505 of this subpart.

§ 447.507 Identification of 5i drugs.

A manufacturer must identify each covered outpatient drug that is a 5i drug that is not generally dispensed through a retail community pharmacy.

(a) *Identification of a 5i drug.* A manufacturer must use the list of FDA's Routes of Administration posted on the CMS Web site to identify each covered outpatient drug that qualifies as a 5i drug.

(b) *Not generally dispensed through a retail community pharmacy.* A manufacturer must determine if the 5i drug is not generally dispensed through a retail community pharmacy based on the percentage of sales to entities other than retail community pharmacies.

(1) A 5i drug is not generally dispensed through a retail community pharmacy if 90 percent or more of the sales of the 5i drug, during the reporting period, were to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies.

(2) A manufacturer is responsible for determining whether a 5i drug is not generally dispensed through a retail community pharmacy on a monthly and quarterly basis.

§ 447.508 Exclusion from best price of certain sales at a nominal price.

(a) *Exclusion from best price.* Sales of covered outpatient drugs by a manufacturer at nominal prices are excluded from best price when purchased by the following entities:

(1) A covered entity as described in section 340B(a)(4) of the PHSA.

(2) An ICF/MR providing services as set forth in § 440.150 of this chapter.

(3) A State-owned or operated nursing facility providing services as set forth in § 440.150 of this chapter.

(4) A public or non-profit entity or facility at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, and provide family planning services described under section of 1001(a) of PHSA, 42 U.S.C. 300.

(5) An entity that—

(i) Is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of that Act or is State-owned or operated; and

(ii) Is providing the same services to the same type of population as a covered entity described in section 340B(a)(4) of the PHSA but is not in receipt of grant funds under that Act.

(b) *Nonapplication.* This restriction does not apply to sales by a manufacturer of covered outpatient drugs that are sold under a master agreement under 38, U.S.C. 8126.

(c) *Rule of construction.* Nothing in this subpart is construed to alter any existing statutory or regulatory prohibition on services for an entity described paragraph (a) of this section, including the prohibition set forth in section 1008 of the PHSA.

§ 447.509 Medicaid drug rebates.

(a) *Determination of rebate amount.*

(1) *Basic rebate for single source drugs and innovator multiple source drugs.* The amount of basic rebate for each dosage form and strength of a single source drug or an innovator multiple source drug is equal to the product of—

(i) The total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) The greater of—

(A) The difference between the AMP and the best price for the dosage form and strength of the drug; or

(B) The AMP for the dosage form and strength of the drug multiplied by one of the following percentages—

(*1*) For a clotting factor, 17.1 percent;

(*2*) For a drug approved by the FDA exclusively for pediatric indications, 17.1 percent; or

(*3*) For all other single source drugs and innovator multiple source drugs, 23.1 percent.

(2) *Additional rebate for single source and innovator multiple source drugs.* In addition to the basic rebate described in paragraph (a)(1) of this section, for each dosage form and strength of a single source drug or an innovator multiple source drug, the rebate amount will be increased by an amount equal to the product of—

(i) The total number of units of such dosage form and strength paid for under the State plan in the rebate period; and

(ii) The amount, if any, by which—

(A) The AMP for the dosage form and strength of the drug for the period exceeds:

(B) The base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug.

(3) *Total rebate.* The total rebate amount for single source drugs and innovator multiple source drugs is equal to the basic rebate amount plus the additional rebate amount, if any.

(4) *Treatment of new formulations.*

(i) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation is the amount computed under paragraphs (a)(1) through (a)(3) of this section for such new drug or, if greater, the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form.

(B) The highest additional rebate (calculated as a percentage of AMP) under this section for any strength of the original single source drug or innovator multiple source drug.

(C) The total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

(ii) The term "line extension" means, with respect to a drug, a new formulation of the drug, such as an extended release product.

(iii) *Identification of line extension drugs.*

(A) The FDA's list of Chemical Types, listed in FDA Drugs in FDA's database, is used to identify the line extension drug and the initial brand name listed drug.

(B) Chemical Type 2, new ester, new salt, or other noncovalent derivative; Chemical Type 3, new formulation; Chemical Type 4, new combination; and Chemical Type 6, new indication are determined to be line extension drugs.

(C) Chemical Type 1, new molecular entity, represents the initial brand name listed drug.

(5) *Limit on rebate.* In no case will the total rebate amount exceed 100 percent of the AMP of the drug.

(6) *Rebate for noninnovator multiple source drugs.* The amount of the rebate for each dosage form and strength of a noninnovator multiple source drug will be equal to the product of—

(i) The total number of units of such dosage form and strength for which payment was made under the State plan for the rebate period; and

(ii) The AMP for the dosage form and strength for the rebate period multiplied by 13 percent.

(b) *Rebates for drugs dispensed through Medicaid managed care organizations (MCOs).*

(1) Manufacturers participating in the Medicaid drug rebate program will pay rebates for covered outpatient drugs dispensed to individuals enrolled in Medicaid MCOs if the MCO is contractually required to provide such drugs.

(2) Manufacturers are exempt from the requirement in paragraph (b)(1) of this section if such drugs are:

(i) Dispensed by health maintenance organizations including MCOs that contract under section 1903(m) of the Act.

(ii) Discounted under section 340B of the PHSA.

(3) Within 30 days of the end of each quarter, a Medicaid MCO that contractually provides covered outpatient drugs dispensed to Medicaid beneficiaries must report to the State the following data:

(i) MCO identifier.

(ii) National Drug Code.

(iii) Period covered.

(iv) Product FDA list name.

(v) Total units.

(vi) Total number of prescriptions.

(vii) Amount reimbursed.

(c) *Federal offset of rebates.* States must remit to the Federal government the amount of the savings resulting from the increases in the rebate percentages.

(1) For single source or innovator multiple source drugs other than blood clotting factors and drugs approved by the FDA exclusively for pediatric indications:

(i) If AMP minus best price is less than or equal to AMP times 15.1 percent, then the offset amount is the full 8 percent of AMP (the difference between 23.1 percent of AMP and 15.1 percent of AMP).

(ii) If AMP minus best price is greater than AMP times 15.1 percent but less than AMP times 23.1 percent, then the offset amount is the difference between AMP times 23.1 percent and AMP minus best price.

(iii) If AMP minus best price is equal to or greater than AMP times 23.1 percent, then there is no offset amount.

(2) For single source or innovator multiple source drugs that are clotting

factors and drugs approved by the FDA exclusively for pediatric indications that are subject to a rebate percentage of 17.1 percent of AMP:

(i) If AMP minus best price is less than or equal to AMP times 15.1 percent, then the offset amount is the full 2 percent of AMP (the difference between 17.1 percent of AMP and 15.1 percent of AMP).

(ii) If AMP minus best price is greater than AMP times 15.1 percent but less than AMP times 17.1 percent, then the offset amount is the difference between AMP times 17.1 percent and AMP minus best price.

(iii) If AMP minus best price is equal to or greater than AMP times 17.1 percent, then there is no offset amount.

(3) For a drug that is a line extension of a single source or innovator multiple source drug that is an oral solid dosage form, the offset amount is the difference between the URA calculation for the drug calculated based on the applicable rebate percentage in section 1927 of the Act prior to the Affordable Care Act and the calculation of the URA for the line extension drug, if greater, in accordance with the Affordable Care Act.

(4) For noninnovator multiple source drugs, the offset amount is equal to 2 percent of the AMP (the difference between 13 percent of AMP and 11 percent of AMP).

§ 447.510 Requirements for manufacturers.

(a) *Quarterly reports.* A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. The quarterly pricing report must include the following:

(1) AMP, calculated in accordance with § 447.504 of this subpart.

(2) Best price, calculated in accordance with § 447.505 of this subpart.

(3) Customary prompt pay discounts, which are reported as an aggregate dollar amount for each covered outpatient drug at the nine-digit NDC level, provided to all wholesalers in the rebate period.

(4) Prices that fall within the nominal price exclusion, which are reported as an aggregate dollar amount and include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) of this subpart for the rebate period.

(5) A manufacturer that fails to submit a quarterly AMP to CMS for a product by the thirtieth day after the end of each rebate period will be subject to civil monetary penalties for each product not reported on the thirty-first day of $10,000 per day per drug.

(b) *Reporting revised quarterly AMP, best price, customary prompt pay discounts, or nominal prices.*

(1) A manufacturer must report to CMS any revision to AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due. Any revision request that exceeds 12 quarters will not be considered, except for the following reasons:

(i) The change is a result of the drug category change or a market date change.

(ii) The change is an initial submission for a product.

(iii) The change is due to termination of a manufacturer from the MDR program for failure to submit pricing data and must submit pricing data to reenter the program.

(iv) The change is due to a technical correction, that is, not based on any changes in sales transactions or pricing adjustments from such transactions.

(v) The change is to address specific underpayments to States, or potential liability regarding those underpayments, as required by CMS or court order, or pursuant to an internal investigation, or an OIG or DOJ investigation.

(2) A manufacturer may report revisions to AMP, best price, customary prompt pay discounts, or nominal prices for a period in excess of 12 quarters from the quarter in which the data were due based on the approval of CMS for good cause.

(3) A manufacturer must report revisions to AMP within the 12-quarter time period, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(c) *Base date AMP report.*

(1) *Reporting period.* A manufacturer may report a revised DRA base date AMP to CMS within the first four full calendar quarters following July 17, 2007.

(2) *Recalculation of the DRA base date AMP.*

(i) A manufacturer's recalculation of the DRA base date AMP must only reflect the revisions to AMP as provided for in § 447.504 of this subpart.

(ii) A manufacturer may choose to recalculate the DRA base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating the DRA base date AMP.

(3) *Reporting a revised Affordable Care Act base date AMP.* A manufacturer may report a revised Affordable Care Act base date AMP to CMS within the first four full calendar quarters following [publication date of the final rule].

(4) *Recalculation of the Affordable Care Act base date AMP.*

(i) A manufacturer's recalculation of the Affordable Care Act base date AMP must only reflect the revisions to AMP as provided for in § 447.504 of this subpart.

(ii) A manufacturer may choose to recalculate the Affordable Care Act base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating the Affordable Care Act base date AMP.

(d) *Monthly AMP.*

(1) *Definition.* Monthly AMP means the AMP that is calculated on a monthly basis. A manufacturer must submit a monthly AMP to CMS not later than 30 days after the last day of each prior month.

(2) *Calculation of monthly AMP.* Monthly AMP is calculated based on § 447.504 of this subpart, except the period covered is based on monthly, as opposed to quarterly, sales.

(i) The monthly AMP is calculated based on the weighted average of prices for all the manufacturer's package sizes of each covered outpatient drug sold by the manufacturer during a month.

(ii) It is calculated as net sales divided by number of units sold, excluding goods or any other items specifically excluded in the statute or regulations. Monthly AMP is calculated based on the best data available to the manufacturer at the time of submission.

(iii) In calculating monthly AMP, a manufacturer must estimate the impact of its lagged price concessions using a 12-month rolling percentage to estimate the value of those discounts.

(3) *Timeframe for reporting revised monthly AMP.* A manufacturer must report to CMS revisions to monthly AMP for a period not to exceed 36 months from the month in which the data were due, except as allowed in paragraph (b)(1) of this section.

(4) *Exception.* A manufacturer must report revisions to monthly AMP within the 36-month time period, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(5) *Terminated products.* A manufacturer must not report a monthly AMP for a terminated product beginning with the first month after the expiration date of the last lot sold.

(6) *Monthly AMP units.* A manufacturer must report the total number of units that are used to calculate the monthly AMP in the same unit type as used to compute the AMP

to CMS not later than 30 days after the last day of each month.

(7) *Failure to report product information, monthly AMP and AMP units.* A manufacturer that fails to submit a monthly AMP and the total number of units that are used to calculate that monthly AMP to CMS for a product by the thirtieth day after the last day of each month will be subject to civil monetary penalty for each product not reported on the thirty-first day of $10,000 per drug per day.

(e) *Certification of pricing reports.* Each report submitted under paragraphs (a) through (d) of this section must be certified by one of the following:

(1) The manufacturer's chief executive officer (CEO).

(2) The manufacturer's chief financial officer (CFO).

(3) An individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in paragraphs (e)(1) through (e)(3) of this section.

(f) *Recordkeeping requirements.*

(1) A manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for that rebate period.

(i) The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations.

(ii) The 10-year timeframe applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised pricing data subsequently submitted to CMS.

(2) A manufacturer must retain records beyond the 10-year period if all of the following circumstances exist:

(i) The records are the subject of an audit, or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.

(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) *Data reporting format.* All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format designated by CMS.

§ 447.511 Requirements for States.

(a) *Invoices submitted to participating drug manufacturers.* Within 60 days of the end of each quarter, the State must bill participating drug manufacturers an invoice which includes, at a minimum, all of the following data:

(1) The State code.

(2) National Drug Code.

(3) Period covered.

(4) Product FDA list name.

(5) Unit rebate amount.

(6) Units reimbursed.

(7) Rebate amount claimed.

(8) Number of prescriptions.

(9) Medicaid amount reimbursed.

(10) Non-Medicaid amount reimbursed.

(11) Total amount reimbursed.

(b) *Data submitted to CMS.* On a quarterly basis, the State must submit drug utilization data to CMS, which will be the same information as submitted to the manufacturers.

(c) *State that has participating Medicaid Managed Care Organizations (MCO).* A State that has participating Medicaid Managed Care Organizations (MCO), which includes covered outpatient drugs in its contracts with the MCOs, must report data described in paragraph (a) of this section for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the MCO and for which the MCO is required under contract for coverage of such drugs under section 1903 of the Act. This data must be identified separately from the data pertaining to drugs that the State reimburses on a fee-for-service basis.

§ 447.512 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, in the aggregate, the amount that would result from the application of the specific limits established in accordance with § 447.514 of this subpart. If a specific limit has not been established under § 447.514 of this subpart, then the rule for "other drugs" set forth in paragraph (b) of this section applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.514 of this subpart must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the following:

(1) AAC plus a professional dispensing fee established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.*

(1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.514 of this subpart does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular beneficiary.

(2) The agency must decide what certification form and procedure are used.

(3) A check off box on a form is not acceptable but a notation like "brand necessary" is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

§ 447.514 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.*

(1) CMS will establish and issue listings that identify and set upper limits for multiple source drugs available for purchase by retail community pharmacies on a nationwide basis that the FDA has rated at least three drug products as pharmaceutically and therapeutically equivalent in its most current edition of "Approved Drug Products with Therapeutic Equivalence Evaluations" (including supplements or in successor publications). Only pharmaceutically and therapeutically equivalent formulations will be used to determine such limit, and such limit will only be applied to those therapeutically equivalent drug products

(2) CMS publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid Program issuances.

(b) *Specific upper limits.* The agency's payments for multiple source drugs identified and listed periodically by CMS in Medicaid Program issuances must not exceed, in the aggregate, prior to the application of any Federal or State drug rebate considerations, payment levels determined by applying for each drug entity a professional dispensing fee established by the State agency plus an amount established by CMS that is equal to 175 percent of the weighted average of the most recently reported monthly AMP using manufacturer submitted utilization data.

(c) *Ensuring a drug is for sale nationally.* To assure that a multiple source drug is for sale nationally, CMS will consider the following additional criteria:

(1) The AMP of a terminated NDC will not be used to set the Federal upper limit (FUL) beginning with the first day of the month after the termination date reported by the manufacturer to CMS.

(2) The monthly AMP units data will be used to calculate the weighted average of monthly AMPs for all multiple source drugs to establish the FUL.

(d) The FUL will be applied as an aggregate upper limit.

§ 447.516 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

§ 447.518 State plan requirements, findings, and assurances.

(a) *State plan.* The State plan must describe comprehensively the agency's payment methodology for prescription drugs, including the agency's payment methodology for drugs dispensed by all of the following:

(1) A covered entity described in section 1927(a)(5)(B) of the Act.

(2) A contract pharmacy under contract with a covered entity described in section 1927(a)(5)(B) of the Act.

(3) An Indian Health Service, tribal and urban Indian pharmacy.

(b) *Findings and assurances.* Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) *Findings.* The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with § 447.514(a) of this subpart, are in accordance with the upper limits specified in § 447.514(b) of this subpart.

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.512 of this subpart.

(2) *Assurances.* The agency must make assurances satisfactory to CMS that the requirements set forth in § 447.512 and § 447.514 of this subpart concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) *Recordkeeping.* The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

(d) *Data requirements.* When proposing changes to the ingredient cost reimbursement or professional dispensing fee reimbursement, States must provide adequate data, including, but not limited to, a State or national survey of retail pharmacy providers or other reliable data which reflects the pharmacy's actual or average acquisition cost as a base to support any proposed change in ingredient cost reimbursement. States must submit to CMS the proposed change in reimbursement and the supporting data through a State plan amendment through the formal review process.

§ 447.520 FFP: Conditions relating to physician-administered drugs.

(a) No FFP is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates.

(1) As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers to secure rebates.

(2) As of January 1, 2007, a State must require providers to submit claims for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

(b) As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the Secretary as having the highest dollar value under the Medicaid Program using NDC numbers to secure rebates.

(c) A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.

§ 447.522 Optional coverage of investigational drugs and other drugs not subject to rebate.

(a) Medicaid coverage of investigational drugs may be provided at State option under section 1905(a)(12) of the Act when such drug has been indicated by the FDA for human trials.

(b) A State agency electing to provide coverage of an investigational drug must include in its State plan a description of the coverage and payment for such drug.

(c) The State plan must indicate that any payments for investigational drugs will be reimbursed in accordance with the FDA final rules at 21 CFR parts 312 and 316 if they are to be eligible to receive FFP for these drugs.

(d) Medicaid coverage of other drugs may be provided at State option under section 1905(a)(12) of the Act provided that they are not covered outpatient drugs or fail to be listed electronically with the FDA.

(e) Investigational drugs and other drugs are not subject to the rebate requirements of section 1927 of the Act provided they do not meet the definition of a covered outpatient drug as set forth in section 1927(k) of the Act.

Authority: Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program.

Dated: March 16, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 16, 2011.

Kathleen Sebelius,

Secretary.

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Exhibit [X] to Health Care Professional Consulting Agreement: Invoice Itemization Requirements

Federal and state spend transparency and disclosure laws (including the Physician Payments Sunshine Act) require that pharmaceutical company X report professional fees and expense reimbursements paid to Covered Health Care Professional Recipients. Our reports must itemize these payments and expenses into predefined categories.

Accordingly, please itemize your professional invoice to include the professional and expense identifiers outlined below. Please include all expense receipts with your invoice.

INVOICE NO. /DATE:	
Professional Identifiers	
Name (including credentials):	
State(s) of Licensure:	
State License Number(s):	
NPI Number:	
Endo Customer ID Number (if known):	
Business Address: (number, street, suite #, city, state/province, zip/postal code, country)	
Telephone Number:	( )
Engagement Information	
Purpose of Engagement:	
Product Related to Engagement:	
Engagement Date(s):	
Engagement Location:	
Name of Endo Business Contact:	
Expense Itemization	**Amount**
Professional Fee:	$
Transportation Total: (including round trip air fare, taxi, parking, tolls, and mileage)	$
Lodging Total:	$
Meal(s) Total:	$
INVOICE TOTAL:	$