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CMS ISSUES PROPOSED RULE RELATING TO MANUFACTURER REBATES AND REIMBURSEMENT AMOUNTS FOR OUTPATIENT PRESCRIPTION DRUGS DISPENSED TO MEDICAID BENEFICIARIES

RESOURCE LINKS

Proposed CMS Rule:
http://www.gpo.gov/fdsys/pkg/FR-2012-02-02/pdf/2012-2014.pdf

Submit Comments to:
http://www.regulations.gov.

IMPORTANT DATE

Comments Due:
April 2, 2012

PART 1 - PROPOSALS RELATING TO MANUFACTURER REBATES

On February 2, 2012, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule ("Proposed Rule") intended to implement changes to the Medicaid Drug Rebate Program ("MDRP") and to reimbursement limits for outpatient drugs covered by Medicaid made by Title II, Subtitle F, of the Patient Protection and Affordable Care Act of 2010,[i] as amended by Section 1206 of the Health Care and Education Reconciliation Act of 2012[ii] (collectively, "ACA"). The Proposed Rule also is intended to implement additional changes made by Section 202 of the Education Jobs and Medicaid Funding Act.[iii] (The Proposed Rule is available at http://www.gpo.gov/fdsys/pkg/FR-2012-02-02/pdf/2012-2014.pdf.) With respect to the MDRP, CMS proposes changes to the manner in which pharmaceutical manufacturers calculate Average Manufacturer Price ("AMP") and Best Price for Medicaid-covered outpatient drugs and the manner in which rebates that manufacturers pay on prescriptions of those drugs dispensed to Medicaid beneficiaries are calculated. With respect to reimbursement, the Proposed Rule not only addresses changes the ACA made to the manner in which reimbursement limits on multiple source drugs are calculated, but also proposes to change one of the metrics that state Medicaid programs use to determine the ingredient cost of all other drugs they cover and to clarify the costs that may be taken into account when setting the dispensing fee they pay to pharmacies. If the changes included in the Proposed Rule are finalized by CMS, the impact to industry stakeholders, including, but not limited to, pharmaceutical manufacturers and pharmacies, would be substantial.

The Proposed Rule identifies a number of areas where CMS expressly seeks comments. CMS will accept comments on these topics and any other topics of interest to stakeholders in the Proposed Rule until April 2, 2012. Comments may be submitted electronically at http://www.regulations.gov.[iv] Comments will be made publicly available.

Due to the number of significant proposals in the Proposed Rule, this issue of *IMPLEMENTING HEALTH AND INSURANCE REFORM* is being provided in two parts. Part 1 discusses proposals relating to the MDRP, and Part 2 discusses proposals relating to reimbursement.

In this Part 1, we first summarize in the chart below how CMS proposes to require manufacturers to calculate AMP and Best Price. We then highlight specific proposals likely to be of particular interest to pharmaceutical manufacturers and summarize proposals and other issues about which CMS explicitly requests comments. We focus primarily on proposals that would implement ACA's amendments to the MDRP statute in a particular way or that do not simply mirror those amendments.

SUMMARY OF PROPOSED AMP AND BEST PRICE CALCULATION METHODOLOGIES

This chart is intended to summarize the transactions involving or otherwise related to covered outpatient drugs identified in the Proposed Rule and the manner in which CMS proposes to require manufacturers to treat those transactions in their AMP and Best Price calculations, based upon our preliminary analysis of the Proposed Rule. The chart does not necessarily address all transactions that may be relevant to AMP and/or Best Price calculations, and CMS's proposed treatment of a transaction would not necessarily apply in every factual scenario. Manufacturers should consult competent legal counsel to assist them in analyzing CMS's proposals, including whether CMS's descriptions of the underlying transactions accurately reflect the manner in which transactions involving their covered outpatient drugs actually are conducted.

Entity/Transaction Associated	Sales Dollars and Units Included in Non-5i[1] AMP?	Price Concession Dollars Deducted from "Net Sales" in Non-5i AMP?	Sales Dollars and Units Included in 5i[2] AMP?	Price Concession Dollars Deducted from "Net Sales" in 5i AMP?	Sale Price (After Deducting Associated Price Concessions) Potentially Set Best Price?[3]
Wholesalers (for distribution to RCPs)[4]	Yes	Yes (*but not* Customary Prompt Pay Discounts)	Yes	Yes (*but not* Customary Prompt Pay Discounts)	Yes
Wholesalers (not for distribution to RCPs)	No	No	No	No	Yes
Customary Prompt Pay Discounts to Wholesalers	N/A	No	N/A	No	Yes
Customary Prompt Pay Discounts to Other Entities	N/A	Yes (if entity is AMP-included)	N/A	Yes (if entity is AMP-included)	Yes
Other Manufacturers (for distribution to RCPs)	Yes	Yes	Yes	Yes	Yes
Other Manufacturers (not for distribution to RCPs)	No	No	No	No	Yes[5]
RCPs	Yes	Yes	Yes	Yes	Yes
"Entities that Conduct Business as Wholesalers or Retail Community Pharmacies"[6]	Yes	Yes	Yes±	Yes±	Yes
Specialty Pharmacies[7]	Yes	Yes	Yes±	Yes±	Yes

1 An "N/A" in this column indicates that the transaction likely does not involve the physical transfer of drugs to the other party. The column to the right describes CMS's proposed treatment of the transaction, which likely involves only the transfer of monetary value. Although transactions of this nature typically do not directly involve the physical transfer of drugs to the entities listed, they nonetheless may relate to drugs sold by manufacturers, usually to third parties (*e.g.,* rebates), but sometimes to the entities listed (*e.g.,* fees). Unless otherwise indicated, with respect to transactions of this nature that CMS proposes be excluded from AMP calculations, CMS does not appear to propose that manufacturers also exclude the sales related to the transactions with the entities listed.

2 See the discussion, below, regarding the proposed circumstances in which manufacturers would use the alternative AMP methodology summarized in this column and the column to the right to calculate AMP values for 5i drugs.

3 A "yes" indicates that CMS proposes that manufacturers include the net price associated with the transaction in their determinations of Best Price *unless that price is subject to another exclusion proposed by CMS* (*e.g.,* a price paid by a charitable pharmacy might set Best Price, but a price paid by a charitable pharmacy that is also a Section 340B covered entity would not). The Proposed Rule also suggests potential factual nuances that could dictate whether manufacturers include the price in their determinations of Best Price (*e.g.,* see the discussion, below, regarding CMS's proposal to permit the exclusion of prices paid by Section 340B covered entities only "where the covered entities meet the conditions set by [the] PHSA"). This chart does not purport to address all such complexities.

4 See the discussion, below, regarding CMS's proposal to require manufacturers to calculate AMP values from "actual sales" to wholesalers for distribution to retail community pharmacies and directly to retail community pharmacies, which potentially would prohibit the "presumed inclusion" of sales to wholesalers in AMP calculations.

5 This may require additional analysis in special cases, such as where product is purchased by the other manufacturer for use in a clinical investigation.

6 Although CMS proposes that manufacturers include in their AMP calculations sales and price concessions to entities that "conduct business as wholesalers or retail community pharmacies," including, but not limited to, "specialty pharmacies," "home infusion pharmacies," and "home healthcare providers," see the discussion, below, regarding the issues that this proposal raises. ±Also see the discussion, below, regarding how such sales might affect manufacturers' assessment of CMS's proposed criteria for identifying 5i drugs "not generally dispensed through retail pharmacies."

7 See *supra*, note 6.

Entity/Transaction Associated	Sales Dollars and Units Included in Non-5i[1] AMP?	Price Concession Dollars Deducted from "Net Sales" in Non-5i AMP?	Sales Dollars and Units Included in 5i[2] AMP?	Price Concession Dollars Deducted from "Net Sales" in 5i AMP?	Sale Price (After Deducting Associated Price Concessions) Potentially Set Best Price?[3]
Home Infusion Pharmacies[8]	Yes	Yes	Yes±	Yes±	Yes
Home Healthcare Providers[9]	Yes	Yes	Yes±	Yes±	Yes
Indian Health Service (post-10/1/92)	No	No	No	No	No
Department of Veterans Affairs (post-10/1/92)	No	No	No	No	No
State Homes Funded Under 38 U.S.C. § 1741 (post-10/1/92)	No	No	No	No	No
Public Health Service (post-10/1/92)	No	No	No	No	No
State AIDS Drug Assistance Programs (as defined in PHSA § 340B)	N/A (if rebate option) No (if direct purchase)	No	N/A (if rebate option) No (if direct purchase)	No	No* **But "Yes" if CE does not meet HRSA's conditions, unless nominal*
DSH Hospitals (as defined in PHSA § 340B)	No	No	No	No	No* **But "Yes" if CE does not meet HRSA's conditions (including GPO restriction), unless nominal*
Children's Hospitals (as defined in PHSA § 340B)	No	No	No	No	Inpatient Orphan Sales: Yes (unless nominal) Outpatient Orphan Sales: No* Inpatient Non-Orphan Sales: Yes (unless nominal) Outpatient Non-Orphan Sales: No* **But "Yes" if CE does not meet HRSA's conditions (including GPO restriction), unless nominal*

[8] See *supra*, note 6.
[9] See *supra*, note 6.

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Entity/Transaction Associated	Sales Dollars and Units Included in Non-5i[1] AMP?	Price Concession Dollars Deducted from "Net Sales" in Non-5i AMP?	Sales Dollars and Units Included in 5i[2] AMP?	Price Concession Dollars Deducted from "Net Sales" in 5i AMP?	Sale Price (After Deducting Associated Price Concessions) Potentially Set Best Price?[3]
Free Standing Cancer Hospitals (as defined in PHSA § 340B)	No	No	No	No	Inpatient Orphan Sales: Yes (unless nominal) Outpatient Orphan Sales: Yes (unless nominal) Inpatient Non-Orphan Sales: Yes (unless nominal) Outpatient Non-Orphan Sales: No* **But "Yes" if CE does not meet HRSA's conditions (including GPO restriction), unless nominal*
Critical Access Hospitals, Rural Referral Centers, and Sole Community Hospitals (each as defined in PHSA § 340B)	No	No	No	No	Inpatient Orphan Sales: Yes (unless nominal) Outpatient Orphan Sales: Yes (unless nominal) Inpatient Non-Orphan Sales: Yes (unless nominal) Outpatient Non-Orphan Sales: No* **But "Yes" if CE does not meet HRSA's conditions, unless nominal*

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Entity/Transaction Associated	Sales Dollars and Units Included in Non-5i[1] AMP?	Price Concession Dollars Deducted from "Net Sales" in Non-5i AMP?	Sales Dollars and Units Included in 5i[2] AMP?	Price Concession Dollars Deducted from "Net Sales" in 5i AMP?	Sale Price (After Deducting Associated Price Concessions) Potentially Set Best Price?[3]
Other PHSA § 340B Covered Entities	No	No	No	No	Inpatient Orphan Sales: Yes (unless nominal) Outpatient Orphan Sales: No Inpatient Non-Orphan Sales: Yes (unless nominal) Outpatient Non-Orphan Sales: No* **But "Yes" if CE does not meet HRSA's conditions, unless nominal*
"Designated" State Pharmacy Assistance Programs	N/A (No, if direct purchase)	No	N/A (No, if direct purchase)	No	No
Other State Pharmacy Assistance Programs	N/A (No, if direct purchase)	No	N/A (No, if direct purchase)	No	Yes
FSS Sales	No	No	No	No	No
TRICARE, Other Depot Prices, Federal Government Single Award Contract Prices	No	No	No	No	No
TRICARE Retail Pharmacy Program	?[10]	No	?	No	No
Sales into the Territories[11]	See applicable entity/transaction	See applicable entity/transaction	See applicable entity/transaction	See applicable entity/transaction	See applicable entity/transaction
Sales Outside of the U.S./Territories	No	No	No	No	No

[10] Although CMS proposes that TRICARE Retail Pharmacy Program prices be treated as prices to the U.S. Department of Defense ("DoD") and, therefore, excluded from the calculation of AMP, CMS does explicitly address whether sales to RCPs that are dispensed to TRICARE beneficiaries and on which manufacturers pay refunds to the DoD would be included in or excluded from AMP. CMS directed manufacturers in previous program guidance that those underlying sales should not be included.

[11] See the discussion, below, regarding CMS's proposal to redefine "States" to include U.S. territories.

Entity/Transaction Associated	Sales Dollars and Units Included in Non-5i[1] AMP?	Price Concession Dollars Deducted from "Net Sales" in Non-5i AMP?	Sales Dollars and Units Included in 5i[2] AMP?	Price Concession Dollars Deducted from "Net Sales" in 5i AMP?	Sale Price (After Deducting Associated Price Concessions) Potentially Set Best Price?[3]
Hospitals (non-PHSA § 340B) (direct and indirect)	No	No	Yes	Yes	Yes
HMOs/MCOs, generally	N/A	No	Yes[12]	Yes	Yes
HMO-/MCO-Operated Pharmacies	No	No	Yes	Yes	Yes
LTC/Nursing Facilities	No	No	Yes	Yes	Yes
LTCF Pharmacies	No	No	Yes	Yes	Yes
Contract Pharmacies for LTCFs	No (where sales can be identified with adequate documentation)	No (where sales can be identified with adequate documentation)	Yes	Yes	Yes
Assisted Living Facilities and "Other Entities where Drugs are Dispensed through a Nursing Facility Pharmacy"	No	No	Yes	Yes	Yes
Mail Order Pharmacies (not including PBM Mail Order Pharmacies)[13]	No	No	Yes	Yes	Yes
Outpatient Surgical Centers	No	No	Yes	Yes	Yes
Outpatient Ambulatory Care Centers	No	No	Yes	Yes	Yes
Outpatient Dialysis Centers	No	No	Yes	Yes	Yes
Outpatient Mental Health Centers	No	No	Yes	Yes	Yes
Other Clinics and Outpatient Facilities	No	No	Yes	Yes	Yes
Government Pharmacies (*e.g.,* federal-, state-, county-, or municipality-owned pharmacy)	No	No	No	No	Yes (unless otherwise excluded, *e.g.,* FSS etc.)
Charitable and/or Not-for-Profit Pharmacies (§ 501(c)(3))	No	No	No	No	Yes
Insurers (if payment is directly to insurer)[14]	N/A	No	N/A	Yes (unless paid to insurer under MDRP)[15]	Yes

[12] There is not an explicit exception for Medicaid drug rebates paid to HMOs/MCOs, as there is for Medicaid drug rebates paid to "insurers." But see, *infra*, note 15.

[13] But see the discussion, below, regarding CMS's proposal that manufacturers include in their AMP calculations sales and price concessions to entities that "conduct business as wholesalers or retail community pharmacies," including, but not limited to, "specialty pharmacies," "home infusion pharmacies," and "home healthcare providers."

[14] CMS proposes to define "insurer" as an entity that does not take possession of drugs and thus would appear to exclude "staff-model" managed care organizations.

[15] It is not clear when Medicaid drug rebates would be paid to an insurer, given that MDRP rebates are paid to the states, even when pertaining to Medicaid MCO utilization.

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Entity/Transaction Associated	Sales Dollars and Units Included in Non-5i[1] AMP?	Price Concession Dollars Deducted from "Net Sales" in Non-5i AMP?	Sales Dollars and Units Included in 5i[2] AMP?	Price Concession Dollars Deducted from "Net Sales" in 5i AMP?	Sale Price (After Deducting Associated Price Concessions) Potentially Set Best Price?[3]
Service Fees (including, without limitation, inventory management fees, product stocking allowances, fees associated with administrative agreements, and patient care programs (such as medication compliance and patient education))[16]	N/A	If a "Bona Fide Service Fee": No If not a "Bona Fide Service Fee" and entity type is included in AMP: Yes If not a "Bona Fide Service Fee" and entity type is not included in AMP: No	N/A	If a "Bona Fide Service Fee": No If not a "Bona Fide Service Fee" and entity type is included in AMP: Yes If not a "Bona Fide Service Fee" and entity type is not included in AMP: No	If a "Bona Fide Service Fee": No If not a "Bona Fide Service Fee": Yes
GPO Administrative Fees[17]	N/A	If a "Bona Fide Service Fee": No If not a "Bona Fide Service Fee" and member type is included in AMP: Yes If not a "Bona Fide Service Fee" and member type is not included in AMP: No	N/A	If a "Bona Fide Service Fee": No If not a "Bona Fide Service Fee" and member type is included in AMP: Yes If not a "Bona Fide Service Fee" and member type is not included in AMP: No	If a "Bona Fide Service Fee": No If not a "Bona Fide Service Fee": Yes
GPO Chargebacks	See applicable member entity	See applicable member entity	See applicable member entity	See applicable member entity	See applicable member entity
Reimbursement for Recalled, Damaged, Expired, or "Otherwise Unsalable" Returned Goods[18]	No?[19]	No	No?	No	Not Clear[20]
PBMs, generally[21]	N/A	No	Yes	Yes	Yes

16 See the discussion, below, regarding "Bona Fide Service Fees."

17 Where a "yes" is indicated in the columns to the right, manufacturers should consider whether to make reasonable assumptions regarding whether to include in AMP and/or Best Price, the entire fee or only that portion that falls outside of the Bona Fide Service Fee test.

18 "Otherwise unsalable" is not a defined term in the Proposed Rule.

19 The Proposed Rule does not clearly address proper treatment of "replacement" product units/sales dollars, where returned product is replaced rather than refunded.

20 Proposed 42 C.F.R. § 447.505(c)(14) specifically would exclude such reimbursement from AMP calculations, but proposed 42 C.F.R. §447.505(d)(1) states that Best Price "is net of … returns … which reduce the price available from the manufacturer."

21 For the alternate AMP methodology for 5i drugs, the Proposed Rule refers to PBMs that are not "insurers." If a PBM is an insurer, see row pertaining to "Insurers."

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Entity/Transaction Associated	Sales Dollars and Units Included in Non-5i[1] AMP?	Price Concession Dollars Deducted from "Net Sales" in Non-5i AMP?	Sales Dollars and Units Included in 5i[2] AMP?	Price Concession Dollars Deducted from "Net Sales" in 5i AMP?	Sale Price (After Deducting Associated Price Concessions) Potentially Set Best Price?[3]
PBM Mail Order Pharmacies	No	No	Yes	Yes	Yes
PBM Administrative Fees	N/A	No	N/A	If a "Bona Fide Service Fee": No If not a "Bona Fide Service Fee": Yes (where PBM is not insurer)	If a "Bona Fide Service Fee": No If not a "Bona Fide Service Fee": Yes
Medicaid Rebates to States (including on Medicaid MCO utilization)	N/A	No	N/A	No (but see notes to "Insurers")	No
Medicaid "Supplemental" Rebates	N/A	No	N/A	No	No
Rebates to Medicaid MCOs (not under the MDRP)	(see HMOs/MCOs)	(see HMOs/MCOs)	(see HMOs/MCOs)	(see HMOs/MCOs)	(see HMOs/MCOs)
Medicare PDPs, MA-PDs, and RDS Plans	N/A (No, if direct purchase)	No	N/A (No, if direct purchase)	No	No
Medicare Part D Coverage Gap Discount Program	N/A	No	N/A	No	No
Hospice (inpatient and outpatient)	No	No	Yes	Yes	Yes
Prisons	No	No	No	No	Yes (unless otherwise excluded, such as under the FSS, or single award contracts)
Physicians (direct sales)	No	No	Yes	Yes	Yes
Physicians (indirect sales)[22]	No	No	Yes	Yes	Yes
Patients (direct sales)	No	No	No	No	No
Free Goods, Not Contingent Upon Any Purchase Requirement	No	No	No	No	No
Coupons	N/A	No	N/A	No	No

[22] But see the discussion, below, regarding CMS's proposal that manufacturers include in their AMP calculations sales and price concessions to entities that "conduct business as wholesalers or retail community pharmacies," including, but not limited to, "specialty pharmacies," "home infusion pharmacies," and "home healthcare providers."

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Entity/Transaction Associated	Sales Dollars and Units Included in Non-5i[1] AMP?	Price Concession Dollars Deducted from "Net Sales" in Non-5i AMP?	Sales Dollars and Units Included in 5i[2] AMP?	Price Concession Dollars Deducted from "Net Sales" in 5i AMP?	Sale Price (After Deducting Associated Price Concessions) Potentially Set Best Price?[3]
Vouchers[23]	No?	No	No?	No	No
Manufacturer-Sponsored Drug Discount Card Programs	N/A	No	N/A	No	No
Free Goods Under Manufacturer-Sponsored Patient Refund/Rebate Programs[24]	No	No	No	No	No
Free Goods Under Manufacturer-Copayment Assistance Programs and PAPs[25]	No?	No	No?	No	No
Sales at Nominal Prices	See applicable entity type	See applicable entity type	See applicable entity type	See applicable entity type	Yes, unless purchased by entity described in 42 C.F.R. § 447.508

23 The Proposed Rule suggests that payments to pharmacies that exceed the value passed through to the patient might impact AMP.
24 See *supra*, note 23.
25 See *supra*, note 23.

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PROPOSALS OF PARTICULAR INTEREST TO PHARMACEUTICAL MANUFACTURERS

A. AMP & Best Price Calculations

- *No "Presumed Inclusion" of Sales to Wholesalers in AMP*

  In regulations promulgated by CMS in 2007 to implement changes to the MDRP made by the Deficit Reduction Act of 2005 ("2007 Regulations"), manufacturers were required to include in their AMP calculations sales to wholesalers that they could not confirm with adequate documentation were sold subsequently to AMP-ineligible entities. CMS now proposes to require manufacturers to calculate AMP values based upon their "actual sales" to "retail community pharmacies" (defined below) and to wholesalers for drugs distributed to retail community pharmacies, and, by doing so, appears to reject the "presumed inclusion" of sales to wholesalers in AMP. CMS is concerned that "presumed inclusion" would result in the inclusion of sales to AMP-ineligible entities, including those that receive discounts not generally available to retail community pharmacies. Manufacturers should consider the ramifications of CMS's proposal, including whether the sales data they already receive would enable them to identify sales to retail community pharmacies or, if not, whether such data could be obtained and would be reliable. Manufacturers also should consider how they would value the units sold to wholesalers that are subsequently sold to retail community pharmacies, particularly in instances in which they have recently changed the price charged to wholesalers.

- *"Specialty" and Other Pharmacies "Conducting Business as Wholesalers or Retail Community Pharmacies"*

  The ACA revised the definition of "Average Manufacturer Price" to require that manufacturers calculate it from sales (directly and through wholesalers) to "retail community pharmacies," rather than to entities in the "retail pharmacy class of trade." The statute defines "retail community pharmacy" as "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" and explicitly excludes "pharmacy[ies] that dispense[] 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."[v]

  CMS proposes to require manufacturers to include in their AMP calculations sales to "entities that conduct business as wholesalers or retail community retail pharmacies, which include[] but [are] not limited to specialty pharmacies, home infusion pharmacies and home healthcare providers." CMS's intent appears to be to ensure that manufacturers are able to calculate AMPs for covered outpatient drugs that are generally not dispensed through the "traditional" types of retail pharmacies named in the statutory definition, but that also are not "inhalation, infusion, instilled, implanted, or injectable drugs" (so-called "5i drugs").[vi] CMS, however, does not propose to include such pharmacies specifically in the definition of "retail community pharmacy" or to limit this provision to non-5i drugs. CMS also does not

propose definitions for "specialty pharmacy," "home infusion pharmacy," and "home healthcare provider." The combined effect of what CMS does and does not propose raises several issues that manufacturers should consider.

First, it is not clear whether manufacturers would be required to treat sales to specialty pharmacies, home infusion pharmacies, and home healthcare providers as sales to retail community pharmacies when assessing whether a 5i drug is "not generally dispensed through retail community pharmacies" (using the process CMS proposes for doing so, which we describe below). If they would, 5i drugs that otherwise might have qualified for the alternate AMP methodology might not, particularly infused 5i drugs, for which a significant volume of sales likely are to home infusion pharmacies.

Second, it is not clear how manufacturers would be required to treat sales to specialty pharmacies that dispense drugs through the mail, in light of the explicit exclusion of mail-order pharmacies from the definition of "retail community pharmacies."

Third, given that this provision applies to sales to "entities that conduct business as wholesalers or retail community retail pharmacies," it is not clear whether manufacturers would be required to allocate sales to specialty pharmacies depending on the type of business they conduct. In other words, would a manufacturer be required to discern whether specialty pharmacies are acting as "wholesalers" (by re-selling the drugs they purchase) or as "retail community pharmacies" (by dispensing the drugs to patients) and to include in their AMPs only sales to specialty pharmacies acting as "retail community pharmacies" and that portion of sales to specialty pharmacies acting as "wholesalers" subsequently purchased by "retail community pharmacies"?

- *Identification of "5i" Drugs "Not Generally Dispensed" Through Retail Community Pharmacies*

CMS proposes that manufacturers characterize their 5i drugs as "not generally dispensed" through retail community pharmacies if 90 percent or more of the sales of a 5i drug is to entities that are not retail community pharmacies. This "90-10 Rule" is adapted from guidance the U.S. Department of Veterans Affairs has given in connection with the calculation of the Non-Federal Average Manufacturer Price. Under CMS's version of this rule, the manufacturer would calculate AMP from sales to retail community pharmacies (comprising less than 10 percent of total sales) and those sales (within the 90+ percent) to specified commercial entities, including mail-order pharmacies, physicians, hospitals, and insurers.

CMS proposes that manufacturers apply its version of the "90-10 Rule" both monthly and quarterly. However, given that CMS proposes that quarterly AMPs continue to be the weighted average of the three monthly AMPs, it is unclear what purpose that quarterly assessment would serve. Also, if sales of a 5i drug to retail community pharmacies were to oscillate around 10 percent month to month, this proposal might result in a quarterly AMP derived from monthly AMPs calculated under different methodologies (*e.g.,* 5i and non-5i).

- *"Authorized Generic" Drugs*

  With respect to brand name drugs with "authorized generic" versions, CMS proposes to require "primary" manufacturers to include sales to "secondary" manufacturers (*i.e.*, the entities licensed to sell the authorized generic versions) in the primary manufacturers' AMP calculations for the brand name drugs, when the secondary manufacturer is acting as a "wholesaler." This appears to be a change from CMS's position as expressed in the 2007 Regulations.[vii] Primary manufacturers should consider whether they have sufficient information to identify those sales to secondary manufacturers that are subsequently sold to retail community pharmacies, given CMS's proposal to prohibit "presumed inclusion" of sales to wholesalers.

- *"Bona Fide Service Fees"*

  The ACA revised the definition of "Average Manufacturer Price" such that manufacturers are required to exclude "bona fide service fees" from their AMP calculations. (The 2007 Regulations required that such fees be excluded from AMP calculations, as well as from Best Price calculations.) The ACA also provided a non-exhaustive list[viii] of types of fees that potentially qualify as "bona fide service fees," without actually defining "bona fide service fees." Although CMS proposes to incorporate the types of fees listed in the statute into the regulatory definition of "bona fide service fee," it also proposes to reinstate for purposes of AMP calculations (and to preserve for purposes of Best Price calculations) the "four-part test" for determining what constitutes a bona fide service fee, established by the 2007 Regulations. That test requires that a "bona fide service fee" be a payment: (1) for an itemized service; (2) that the manufacturer would otherwise perform itself or engage a third party to perform; (3) that reflects the fair market value of that service; and (4) that the recipient does not pass on, in whole or in part, to another entity. In doing so, CMS appears to be taking the position that no type of fee, regardless of its name, is subject to blanket exclusion.

- *Returns*

  In the 2007 Regulations, manufacturers were not required to deduct returns from their AMP-eligible sales if those returns were made "in good faith," which CMS defined as in accordance with the manufacturer's established returns policy that complies "with customary acceptable business practices and applicable laws and regulations."[ix] The ACA revised the MDRP statute to require that manufacturers exclude from their AMP calculations "reimbursement . . . 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."[x] CMS proposes to incorporate the ACA's exclusion and states in the preamble to the Proposed Rule that "the value of returned goods themselves" would be excluded from AMP calculations when returned in "good faith." Manufacturers should consider the potential implications of CMS's statement and, more generally, how they would implement the proposals related to returned goods, including, for example, how to address the value and units associated with returned and/or replacement goods in their AMP calculations.

- *"Smoothing" of Lagged Price Concessions*

  CMS proposes to reestablish its requirement that manufacturers estimate the value of lagged price concessions related to AMP-eligible sales in a given calculation period (using a 12-month rolling average methodology).[xi] This process, commonly referred to as "smoothing," mirrors the process that CMS described in sub-regulatory guidance issued in February 2011.[xii] Both the 2011 guidance and the Proposed Rule require the use of data from the most recent "12-month period," but neither specifies whether that period includes the month for which the AMP is being calculated.

- *Best Price Exclusion for Sales to Section 340B Covered Entities*

  CMS proposes that manufacturers exclude from their Best Price calculations "[p]rices to [Section] 340B covered entities," which include "[p]rices charged under the [Section] 340B drug pricing program to a covered entity described in section 1927(a)(5)(B) of the [Social Security] Act" and "[a]ny inpatient prices charged to [disproportionate share] hospitals described in section 340B(a)(4)(L) of the [Public Health Service Act ("PHSA")]."[xiii]

  In the preamble to the Proposed Rule, CMS states that it is proposing that "manufacturers can exclude only drugs purchased under the 340B Drug Pricing program from their best price calculation[s] where the covered entities meet the conditions set by [the] PHSA." CMS appears concerned that "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." This proposal raises several interesting issues with respect to statutory interpretation and implementation that manufacturers should consider and possibly address in their comments. For example, manufacturers should consider whether they would be able to identify covered purchased by Section 340B covered entities for use in inpatient settings or, potentially, in other circumstances that do not "meet the conditions set by [the] PHSA."

B. Unit Rebate Amount Calculations

- *Drugs Approved Under "Original New Drug Applications"*

  CMS proposes 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 [federal Food, Drug, and Cosmetics Act ("FDCA")] for purposes of approval by the FDA for safety and effectiveness." The proposal would appear to require that all drugs marketed under NDAs submitted under Section 505 of the FDCA be categorized as either "single source" or "innovator multiple source" and that, accordingly, that their Unit Rebate Amounts ("URAs") be calculated using the methodology that results in relatively higher rebate payments.

  Manufacturers that relied on CMS's 1995 proposed definition of "original NDA"[xiv] to determine the drug category for each of their covered outpatient drugs should consider the implications of CMS's current proposal, including, but not limited to: whether it would affect any of their drugs' drug category designations; if so, the financial implications of

prospectively calculating URAs for those affected drugs under the methodology for "single source" and "innovator multiple source" drugs; and whether they also would be required to apply the definition of "original NDA" retroactively, *i.e.*, to pay the states the difference between the aggregate amount they previously paid in MDRP rebates for affected drugs and the aggregate rebate liability calculated using the methodology for "single source" and "innovator multiple source" drugs.

- *Rebates for "Line Extensions"*

  The ACA revised the MDRP statute to require that the "additional rebate" component of URAs for covered outpatient drugs that are "line extensions" of "oral solid dosage form" covered outpatient drugs (which CMS refers to as "initial brand name listed drugs") take into account the additional rebates of the initial brand name listed drugs. CMS proposes that line extensions be identified by reference to the "chemical types" assigned by the FDA, with line extensions including covered outpatient drugs assigned to Chemical Types 2 (a new ester, salt, or other noncovalent derivative), 3 (new formulation), 4 (new combination), and 6 (new indication). CMS specifies that, under this proposal, line extensions would not include new strengths of initial brand name listed drugs.

  Under CMS's proposed methodology for identifying line extensions, a drug could be a line extension even if it were manufactured by another manufacturer. For example, CMS specifies that line extensions would include drugs marketed under NDAs submitted in accordance with Section 505(b)(2) of the FDCA, which establishes the process for submitting NDAs that reference clinical studies "that 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" they were conducted. Accordingly, a manufacturer's liability for such a line extension's "additional rebates" potentially would be based on the prices that its competitor offered for the initial brand name listed drug.

  It appears that CMS's proposal would apply to products currently marketed that fall within the definition of "line extension." Manufacturers should closely review their entire product portfolios (including relevant FDA "Chemical Type" designations) to identify the products that would be either initial brand name listed drugs or line extensions under CMS's proposal and the potential implications of those designations, both on their MDRP rebate liability and on their MDRP-related procedures.

  Separately, the ACA revised the MDRP statute to include a methodology for calculating quarterly "additional rebates" for line extensions of oral solid dosage form drugs.[xv] CMS proposes to codify that methodology in a regulation and provides an example of how to perform that methodology. Manufacturers may wish to closely review CMS's "example" and consider whether it is consistent with the statute.

C. Drugs Subject to MDRP Rebates

- *Redefining "States" to Include U.S. Territories*

  CMS proposes to revise the current definition of "States" and "United States" to include, in addition to the 50 states and the District of Columbia, Puerto Rico, the U.S. Virgin Islands,

Guam, the Northern Mariana Islands, and American Samoa. This proposal would require manufacturers to pay rebates on utilization of their covered outpatient drugs dispensed to Medicaid beneficiaries in the territories (under fee-for-service or managed care plans). (According to data from the Congressional Research Service, in 2008, the combined Medicaid-enrolled population of the territories was just under one million (996,819).[xvi]) In addition, manufacturers would have to include sales to AMP- and Best Price-eligible entities located in the territories in those respective calculations.

CMS proposes that the Medicaid managed care data requirements, discussed below, not be mandatory for the newly added territories until one year after the first day of the first full quarter after the publication of the final rule. However, it is not clear whether utilization by Medicaid managed care plans in such territories will be eligible for rebates back to the effective date of the final rule.

- *Utilization by Enrollees in Medicaid Managed Care Organizations*

The ACA extended MDRP rebates to units of covered outpatient drugs dispensed to Medicaid managed care plan enrollees and required plan sponsors to report such utilization to the states "on a periodic basis as specified by the Secretary." CMS proposes to require Medicaid MCO plan sponsors to report this utilization "within 30 days of the end of each quarter" and to include in those reports, among other things, the National Drug Code ("NDC"), the "period covered," the total number of units and of prescriptions, and the amount reimbursed. However, CMS does not explicitly limit the utilization included in these quarterly reports to units that are dispensed to plan enrollees only during the preceding quarter, and the requirement to report the "period covered" at least suggests that CMS might intend to permit these reports to include utilization from earlier quarters. Manufacturers should consider whether to request clarification on this issue in order to have a better understanding of the extent of their rebate obligations with respect to utilization by enrollees in Medicaid MCO plans.

D. Manufacturers' Reporting Obligations

- *Related to "Covered Outpatient Drug" Status*

Although the ACA did not revise the longstanding statutory definition of "covered outpatient drug,[xvii] CMS proposes that a drug be considered a "covered outpatient drug" only if it is required to have an NDC assigned to it under applicable FDA regulations and is electronically listed with the FDA. To facilitate CMS's ability to confirm compliance with these proposed criteria, CMS further proposes to require manufacturers to report to CMS the reference number for the FDA-approved application under which each of its drugs is marketed and, for any drug that is permissibly marketed outside of an FDA-approved application, evidence demonstrating that the product meets the definition of "covered outpatient drug."

- *Related to "Line Extensions"*

CMS proposes to require manufacturers to identify and report to CMS the NDCs of their drugs that are line extensions or for which a line extension has been approved. When

different manufacturers distribute the original drug and a line extension, CMS explains that it expects those manufacturers to exchange whatever information is necessary to calculate URAs for their respective drugs accurately. (Although URA calculations for line extensions take into account price information for the initial brand name listed drugs, it does not appear that the reverse is true.)

- *Base Date AMP Recalculations*

  CMS proposes to allow manufacturers to recalculate the Base Date AMPs for their covered outpatient drugs to account for changes in the AMP calculation methodology made by the ACA that would be codified at 42 C.F.R. § 447.504, once finalized, but only if they use "actual and verifiable pricing records." This proposal is intended to prevent the imposition of artificially inflated "additional rebates" that could result from the comparison of a drug's quarterly AMP (calculated under the post-ACA methodology) and its Base Date AMP (calculated under a pre-ACA methodology). Manufacturers would have four full calendar quarters after the publication date of the final rule to submit re-calculated Base Date AMPs to CMS.

  CMS, however, does not specify what the "effective date" of a recalculated Base Date AMP would be. In other words, it is not clear whether a recalculated Base Date AMP would be used only in *prospective* rebate calculations (after it has been submitted to CMS) or would be applied retroactively to the first quarter after ACA's changes to the AMP calculation methodology went into effect on October 1, 2010 (the fourth quarter of 2010), with manufacturers having the ability to recoup any resulting "overpayments" to the states.

  Manufacturers should consider whether they would have "actual and verifiable pricing records" upon which to base a restated Base Date AMP. This may present challenges for some companies, in light of CMS's proposal to require manufacturers to include in their AMP calculations only "actual" sales to retail community pharmacies and to prohibit the "presumed inclusion" of sales to wholesalers that do not generate chargebacks to manufacturers.

- *Restatements*

  CMS proposes to require restatements or corrections to manufacturer-reported information *beyond* 12 quarters in five circumstances: (1) when the change would be to a drug's "drug category" or "market date"; (2) when the change would relate to an initial submission for a product; (3) when the information relates to a drug deleted from CMS's database following termination of its manufacturer from the MDRP, upon that manufacturer's reentry to the program; (4) when the change relates to a technical error (*e.g.*, an error made when the information was originally entered) but does not reflect changes in the data originally used to calculate that information; and (5) when the change addresses an underpayment of MDRP rebates, or potential liability arising from such underpayment, as required by CMS, applicable law or regulations, or an investigation conducted by the Office of Inspector General ("OIG") or the U.S. Department of Justice. CMS is considering whether to impose a time limit (more than 12 quarters) that would apply in any or all of these circumstances, but has not proposed one.

In addition, CMS states that it "plans 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 limit to address underpayments and potential liability regarding those underpayments that may extend outside that 12-quarter period" and invites comments on that option. (CMS contemplates that this latter option, if proposed, would be a permissive, not mandatory.) It is not apparent, however, how this option would differ from the circumstance described above in (5), given that they both relate to redressing past noncompliance, unless the former would relate specifically to methodological changes that CMS does not intend to include within the scope of the latter.

- *Timeliness of Submissions & Compliance with Other Program Requirements*

  CMS reiterates in the Proposed Rule that manufacturers that fail to comply with their monthly and quarterly reporting obligations in a timely manner (*i.e.*, within 30 days of the end of the month or quarter, as applicable) will be referred to the OIG for possible imposition of civil monetary penalties (*i.e.*, $10,000 for each day that information *for each drug* is late). CMS previously announced its cooperation with the OIG to enforce the reporting deadline more vigorously in August 2010.[xviii]

  In the Proposed Rule, CMS states that it is considering whether to develop additional guidance regarding the circumstances in which it might use its authority to suspend or terminate a manufacturer's MDRP agreement to address untimely or noncompliance with reporting obligations or other MDRP requirements and the procedures to be followed when it took such an action.

* * *

As we noted in the introduction, the Proposed Rule includes a number of provisions regarding the manner in which reimbursement limits for Medicaid covered outpatient drugs are calculated, including, for example, a proposal to require that state Medicaid programs use "Actual Acquisition Cost" ("AAC"), rather than "Estimated Acquisition Cost," setting reimbursement amounts for covered outpatient drugs generally, and several proposals implementing the ACA's changes related to "federal upper limits" ("FULs") on reimbursement amounts that CMS is required to establish for multiple source drugs in certain circumstances. Although these proposals are addressed in greater detail in Part 2 of this issue of *IMPLEMENTING HEALTH AND INSURANCE REFORM*, we emphasize here that manufacturers should review these proposals for potential financial and business implications, with particular regard for the possible impact of an AAC-based reimbursement system on their pricing and discounting practices.

PROPOSALS AND OTHER ISSUES ABOUT WHICH CMS REQUESTS COMMENTS

Although comments may be submitted regarding any aspect of the Proposed Rule, CMS specifically requests comments on the following proposals and other issues. For completeness, we summarize below the requests pertaining both to the MDRP and to Medicaid prescription drug reimbursement.

- Definition of "Covered Outpatient Drug": CMS requests comments on its proposal to require the submission of evidence demonstrating covered outpatient drug status for drugs that do not have approved applications but nonetheless satisfy the statutory definition and on drugs or classes of drugs that this may describe.

- Definition of "States"/"United States": CMS requests comments on its proposed redefinition of these terms to include the territories.

- Definition of "Wholesaler": CMS seeks information regarding further data sources or definitions that could be applied to clarify the scope of the term.

- Apparent prohibition of "presumed inclusion" of sales to wholesalers in AMP: CMS requests comments on its proposal to require manufacturers to calculate AMP values based upon their actual sales (directly or indirectly) to retail community pharmacies, apparently without the ability to presume that sales to wholesalers are for drugs distributed to retail community pharmacies, and on distribution data concerning sales from wholesalers to retail community pharmacies that might be available to manufacturers.

- Returned goods excluded from AMP calculations: CMS requests comments on its proposal to have manufacturers rely on standard industry practice to identify drugs that are recalled, damaged, expired, or unsalable, rather than to define those terms or to provide examples of goods that would qualify as "unsalable."

- Line extensions: CMS requests comments on many of its proposals related to URA calculations for line extensions, including the formulations that would qualify as line extensions (*e.g.,* formulations that incorporate abuse deterrent technologies would be considered line extensions, but formulations with different strengths would not), the use of the FDA's "Chemical Type" categories to identify line extensions, and the process for establishing and updating a master list of initial brand name listed drugs and line extensions.

- "Not generally dispensed through a retail community pharmacy": CMS requests comments on its proposal to establish a 90-percent threshold in the methodology manufacturers would use to identify 5i drugs subject to the alternate AMP methodology, on a more appropriate threshold, and on its proposal to require evaluation on a monthly and quarterly basis.

- Failure to report AMP in a timely manner: CMS requests comments regarding appropriate terms and procedures for suspension and termination for manufacturers that do not report quarterly AMP in a timely manner or that are otherwise out of compliance with MDRP requirements.

- Restatements: In connection with its proposal to permit manufacturers to request to restate certain pricing information outside of the otherwise applicable 12-quarter period, CMS requests

comments on whether it should establish some other time limit for those restatements and, if so, what that time limit should be.

- Restatements: CMS requests comments on its plan to establish a "good cause option" to allow manufacturers to restate previously reported AMP and Best Price values outside of the 12-quarter time limit.

- FULs for multiple source drugs: CMS requests comments on its proposal to establish a FUL for pharmaceutically and therapeutically equivalent multiple source drugs once the third such drug (*i.e.,* usually the second generic version) has launched, without confirming that all three are "nationally available" to all retail community pharmacies, provided that retail community pharmacies are able to purchase at least one of those drugs, and on specific instances where such drug products are not available for purchase by retail community pharmacies on a nationwide basis

- Smoothing of FULs: CMS requests comments on its decision not to propose to smooth FULs derived from monthly AMPs before using them to establish ingredient cost reimbursement limits, including whether a smoothing process is necessary, the benefits of using a smoothing process, and the options for performing a smoothing process.

- Reimbursement based on AAC: CMS requests comments on the practicality of requiring each state to conduct a survey of pharmacies' acquisition costs for use in establishing ingredient cost reimbursement amounts based on AAC; on the frequency with which such a survey should be conducted; on how closely ingredient cost reimbursement amounts should conform to survey data (*i.e.,* permissible deviations) and the use of averaged acquisition costs; on using AMP as a proxy for AAC, including whether an appropriate mark-up factor should be applied; and on other possible methods for determining ingredient costs.

- Reimbursement for Section 340B Covered Entities and Indian Health Service ("IHS") and tribal and urban Indian organization pharmacies: In connection with its proposal to require states to have specific methodologies for establishing reimbursement amounts paid to Section 340B Covered Entities and IHS and tribal and urban Indian organization pharmacies, CMS requests comments on methodologies other than reimbursing Section 340B Covered Entities at a cost that would meet the AAC requirements and on appropriate payment levels for IHS and tribal and urban Indian pharmacies.

NEXT STEPS

Pharmaceutical manufacturers, pharmacies, and other key stakeholders should take advantage of this important opportunity to provide comments to CMS on the Proposed Rule. In particular, manufacturers should consider the potential financial implications of the Proposed Rule with respect to their products and implementation costs, including the potential impact of the Proposed Rule on their operations, systems, policies, and financial projections/budgeting. Given the significance of these calculations and the impact of the definitions on reimbursement, stakeholders are urged to devote significant attention to responding to CMS's request for comments. Epstein Becker Green is available to assist with drafting and submitting comments to the Proposed Rule.

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[i] Pub. L. 111-148 (Mar. 23, 2010).
[ii] Pub. L. 111-152 (Mar. 30, 2010).
[iii] Pub. L. 111-226 (Aug. 10, 2010).
[iv] The Proposed Rule also provides information related to the submission of comments by regular mail, express mail, and hand delivery.
[v] 42 U.S.C. § 1396r-8(k)(10).
[vi] The ACA revised the MDRP statute to permit manufacturers of "5i drugs" that are "not generally dispensed through a retail community pharmacy" to calculate AMP using an alternate methodology.
[vii] Under the 2007 Regulations, CMS directed that primary manufacturers include their sales of authorized generic drugs in their AMP calculations only when sold "directly to a wholesaler" (which, under the 2007 Regulations, would not include a manufacturer that repackaged/relabeled). *See* 72 Fed. Reg. 39,141, 39,227 (Jul. 17, 2007). The reason for the change appears to be differences between the definition of "wholesaler" added to the MDRP statute by the ACA and the definition CMS adopted in the 2007 Regulations.
[viii] This list includes 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).
[ix] *See* 72 Fed. Reg. at 39,186.
[x] 42 U.S.C. § 1396r-8(k)(1)(B)(i)(III).
[xi] This requirement was technically withdrawn from the regulations in 2010. *See* 75 Fed. Reg. 69,591 (Nov. 15, 2010).
[xii] *See* CMS, Medicaid Drug Rebate Program Manufacturer Release No. 83 (Feb. 3, 2011), *available at* http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Program-Releases.html.
[xiii] Emphasis added.
[xiv] *See* 60 Fed. Reg. 48442 (Sept. 19, 1995).
[xv] 42 U.S.C. § 1396r-8(k)(2)(C).
[xvi] *See* Government Accountability Office, "Federal Medicaid and CHIP Funding in the U.S. Insular Areas," (GAO-09-558R), at 10 tbl. 2 (June 30, 2009) (citing "Congressional Research Service Estimates of the Medicaid Populations in Each Insular Area, 2008"). The territories' combined 2008 Medicaid population was larger than that of 32 states and the District of Columbia and was comparable to the 2008 Medicaid population of Alabama (908,600), New Jersey (976,100), Missouri (1,023,900), and Wisconsin (1,028,300). *See* The Henry J. Kaiser Family Foundation, "State Health Facts," *available at* http://www.statehealthfacts.org. (These populations presumably include Medicare-Medicaid "dual eligible" beneficiaries, whose primary outpatient prescription drug coverage is provided under Medicare Part D, although manufacturers still pay rebates on covered outpatient drugs for which Medicaid has paid any portion of the cost, including the beneficiaries' Medicare Part D co-payments.)
[xvii] The MDRP statute defines "covered outpatient drugs" to include prescription drugs and biologicals (except vaccines) marketed under NDAs, ANDAs, and BLAs approved by the FDA, drugs without FDA-approved applications that are subject to ongoing DESI review, and, at a state's election, over-the-counter drugs when dispensed pursuant to physicians' prescriptions.
[xviii] *See* CMS, Medicaid Drug Rebate Program Manufacturer Release No. 81 (Aug. 11, 2010), *available at* http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Program-Releases.html.

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