SPECIAL ALERT

HEALTH CARE AND LIFE SCIENCES

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CMS Issues Final Rule Relating To Medicaid Payments For Outpatient Prescription Drugs

On July 17, 2007, the Centers for Medicare & Medicaid Services ("CMS") published a final rule ("Final Rule")[1] intended to clarify, compile and synthesize certain existing regulatory guidance relevant to, among other things, calculations required by the Medicaid Drug Rebate Program under Section 1927 of the Social Security Act ("SSA") and Medicaid payment for outpatient prescription drugs.[2] By way of background, prior to the issuance of the Final Rule, CMS guidance with respect to the average manufacturer price ("AMP") calculation was scattered among numerous subregulatory sources, including the Medicaid Drug Rebate Agreement, the Medicaid Drug Rebate Operational Training Guide, various CMS letters and releases to participating pharmaceutical manufacturers (or "labelers") and the states and a 1995 proposed rule that was never finalized. Section 6001(c)(3)(B) of the Deficit Reduction Act of 2005 ("DRA") required CMS to issue "a regulation that clarifies the requirements for, and manner in which, average manufacturer prices are determined under section 1927 of the Social Security Act."

The Final Rule addresses the following topics: (1) the manner in which pharmaceutical manufacturers calculate Average Manufacturer Price ("AMP") and Best Price ("BP"); (2) pharmaceutical manufacturer reporting and recordkeeping requirements; (3) the establishment of Federal Upper Limit ("FUL") payment amounts for multiple source drugs; and (4) certain information that must be set forth on payment claims submitted to states for physician-administered drugs in order for a state to receive federal contributory funds. With certain exceptions, the effective date of the Final Rule is October 1, 2007; a more detailed implementation timetable is included below. CMS explains that "this rule is not designed to delay the effective date with respect to statutory provisions, regulations or policies that are already in effect" and that "existing requirements that remain unchanged in this final rule will continue in force." [3]

The Final Rule differs in several respects from the proposed rule issued by CMS on December 22, 2006 ("Proposed Rule")[4] as well as from previously issued CMS guidance. This Client Alert provides an overview of the Final Rule, with a particular emphasis on its impact on pharmaceutical manufacturer AMP and BP calculations.

SIGNIFICANT DATES

January 1, 2007

- ✓ Date established by DRA for innovator manufacturers to begin accounting for sales of authorized generic drugs in AMP and BP calculations, as appropriate.

July 17, 2007

- ✓ Publication date of the Final Rule in the *Federal Register*.

October 1, 2007

- ✓ Effective date of the Final Rule.

October 1, 2007 – October 31, 2007

- ✓ First monthly reporting period under the Final Rule.*

October 1, 2007 – December 31, 2007

- ✓ First quarterly reporting period under the Final Rule.*

November 30, 2007

- ✓ Manufacturers report October 2007 AMPs calculated under the Final Rule.*

December 30, 2007

- ✓ FULs published based on new October AMPs.*
- ✓ Manufacturers report November 2007 AMPs calculated under the Final Rule.*

January 1, 2008

- ✓ Date that the states must require providers to include NDCs for the 20 multiple source physician-administered drugs identified annually by CMS on payment claim forms.

January 14, 2008

- ✓ Due date for submission to CMS of public comments on the method CMS will use to identify "outlier AMPs" when establishing FULs for multiple source drugs.

January 30, 2008

- ✓ Manufacturers report 4Q07 AMPs calculated under the Final Rule.*
- ✓ Manufacturers report December 2007 AMPs calculated under the Final Rule.*
- ✓ FULs based on October AMP takes effect after 30 day period for states to implement.*
- ✓ FULs published based on November AMPs.*

September 30, 2008

- ✓ Date that manufacturers choosing to revise "base date AMPs" must submit revised values to CMS. Revised base date AMPs will take effect prospectively beginning in the quarter in which they are reported.

**** Expected date, based on previous timeframes published by CMS.***

Summary Chart of AMP & BP Calculation

The following chart summarizes significant components of the Final Rule's guidance regarding the treatment of transactions for AMP and BP calculations. The Final Rule does not define the terms "include," "not include" and "exclude." Accordingly, we do not use this terminology. This chart assumes that the AMP calculation begins with gross ex-factory sales dollars. This chart also is based upon the following language in the preamble to the Final Rule:

> "*Response:* Net sales should be calculated as gross sales less cash discounts allowed and other price reductions (other than the rebates or price reductions excluded by the statute or regulations) which reduce the amount received by the manufacturer. We have defined AMP to center on the concept of a transaction, such that any given transaction includes both the "sale" and any discounts, rebates, or other price concessions associated with that sale. In certain instances, the statute or regulations specifically exclude from the calculation of AMP either certain portions of a transaction or entire transactions with certain entities. Absent such specific exclusions, we believe that manufacturers should calculate AMP by matching sales with their associated price concessions. In the absence of specific guidance, a manufacturer may make reasonable assumptions in its calculations, consistent with the general requirements and the intent of the Act, Federal regulations, and its customary business practices."[5]

PRELIMINARY SUMMARY OF FINAL RULE IMPLICATIONS FOR SIGNIFICANT COMPONENTS OF AMP AND BP CALCULATIONS

Entity/Transaction	Associated Sales Dollars Deducted From "Gross Sales" for AMP?	Associated Price Concession Dollars Deducted From "Gross Sales" for AMP?[i]	Associated Units Deducted From "Total Units" for AMP?	Sales Price (After Deducting Associated Price Concessions) Potentially Set BP?[ii]
Wholesalers	No[iii]	Yes[iii]	No[iii]	Yes
Wholesalers/Distributors that Relabel the Drug Under the Purchaser's NDC	Yes	No	Yes	No, unless that entity also is an HMO or other nonexcluded entity
Other Manufacturers that do not Repackage/Relabel the Drug Under the Purchaser's NDC (includes private labeling)	No	Yes	No	Yes

i Fees that qualify as "bona fide service fees" as defined in the Final Rule are not treated as price concessions.

ii Note that there may be some overlap between the rows. If an entity or transaction is excluded from best price (i.e., does not potentially set a best price) under any one of the rows, it should be treated as excluded.

iii Except for those sales that can be identified with adequate documentation as being subsequently sold to entities outside the retail pharmacy class of trade. Additionally, customary prompt pay discounts are "excluded" meaning that such discounts shall *not* be deducted from Gross Sales for AMP purposes.

This chart is intended to serve as a summary of the guidance provided in the Final Rule. It is not an exhaustive summary, nor is it intended to address every factual scenario. Further, it is not intended in any way to serve as a substitute for legal advice or counsel. We encourage you to consult your legal adviser for counsel relating to the Final Rule and the interpretation thereof. Specific factual scenarios may result in a different outcome than set forth in this summary chart.

Entity/Transaction	Associated Sales Dollars Deducted From "Gross Sales" for AMP?	Associated Price Concession Dollars Deducted From "Gross Sales" for AMP?[i]	Associated Units Deducted From "Total Units" for AMP?	Sales Price (After Deducting Associated Price Concessions) Potentially Set BP? [ii]
Hospital Outpatient Sales (direct or indirect)	No[iv]	Yes[iv]	No[iv]	Yes
Hospital Inpatient Sales (direct or indirect, including hospital sales where outpatient use cannot be identified with adequate documentation)	Yes	No	Yes	Yes
Retail Pharmacies	No	Yes	No	Yes
Mail Order Pharmacies (includes PBM Mail Order)	No	Yes	No	Yes
Patients (direct sales only)	No	Yes	No	Yes
Sales to Patient Assistance Programs	Yes	No	Yes	No (if goods are provided free of charge)
Manufacturer Coupons	Yes[v]	No[v]	Yes[v]	No[v]
Manufacturer Vouchers	Yes	No	Yes	No
Manufacturer-Sponsored Drug Discount Card Programs	Yes	No	Yes	No
Outpatient Facilities (e.g., clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers)	No	Yes	No	Yes
Home Infusion Providers	No	Yes	No	Yes
Specialty Pharmacies	No	Yes	No	Yes
Home Health Care Providers	No	Yes	No	Yes
Physicians	No	Yes	No	Yes
Medicare Part D Plan or a Medicare Advantage Prescription Drug Plan (MA-PD)	No	No	No	No
Medicare Qualified Retiree Prescription Drug Plan	No	No	No	No

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[iv] Except for those sales that cannot be identified with adequate documentation as being used in the outpatient pharmacy for outpatient use (for example, a hospital outpatient department, clinic, or affiliated entity).

[v] But only to the extent that the full value of the coupon is passed on to the consumer and the redeeming pharmacy, agent, or other entity does not receive any price concession.

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Entity/Transaction	Associated Sales Dollars Deducted From "Gross Sales" for AMP?	Associated Price Concession Dollars Deducted From "Gross Sales" for AMP?[i]	Associated Units Deducted From "Total Units" for AMP?	Sales Price (After Deducting Associated Price Concessions) Potentially Set BP?[ii]
State Children's Health Insurance Program (SCHIP) (Title XIX, Medicaid)	No	No	No	No
State Children's Health Insurance Program (SCHIP) (Title XXI, Non-Medicaid)	No	No	No	Yes
State Pharmaceutical Assistance Programs (SPAPs)	No[vi]	No[vi]	No[vi]	No[vii]
Health Maintenance Organizations (HMOs) and Managed Care Organizations (MCOs) that do not Purchase or Take Possession of Drugs	No	No	No	Yes
HMOs and MCOs that Purchase or Take Possession of Drugs (e.g., "staff" model entities and HMO/MCO-operated pharmacies)	Yes	No	Yes	Yes
Medicaid (including CMS authorized Supplemental Rebates)	No	No	No	No
Indian Health Service (IHS), Department of Veterans Affairs (DVA), State Homes Receiving Funds Under 38 U.S.C. 1741, Department of Defense (DoD), Public Health Service (PHS), or Covered Entities Described in Section 1927(a)(5)(B) of the SSA (including inpatient prices charged to hospitals described in Section 340B(a)(4)(L) of the PHSA)[viii]	Yes	No	Yes	No
Other Third Party Payers that do Not Directly Purchase Drugs	No	No	No	Yes
Federal Supply Schedule (FSS) Prices	Yes	No	Yes	No

vi If SPAP acts as a third-party payer and does not purchase or take possession of or title to the drugs.

vii If SPAP meets criteria set forth in CMS Manufacturer Release # 68.

viii If on or after October 1, 1992.

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Entity/Transaction	Associated Sales Dollars Deducted From "Gross Sales" for AMP?	Associated Price Concession Dollars Deducted From "Gross Sales" for AMP?[i]	Associated Units Deducted From "Total Units" for AMP?	Sales Price (After Deducting Associated Price Concessions) Potentially Set BP? [ii]
Federal Government Agency Depot Prices (including TRICARE other than TRRx) and Single Award Contract Prices	Yes	No	Yes	No
Long-Term Care Facilities, Including Nursing Facility Pharmacies[ix]	Yes	No	Yes	Yes
Hospices (inpatient and outpatient)	Yes	No	Yes	Yes
Veterinarians	Yes	No	Yes	Yes
Prisons	Yes	No	Yes	Yes
State, County, and Municipal Entities	Yes	No	Yes	Yes
Sales Outside the 50 States and the District of Columbia	Yes	No	Yes	No
Free Goods, Not Contingent Upon Any Purchase Requirement	Yes	No	Yes	No
Sales at Nominal Prices[x]	No	Yes	No	Yes
Returned or Replaced Goods[xi]	No	No	No	Case-by-case
PBMs (non-mail order)	No	No	No	No, unless designed to be passed on to provider or health plan[xii]
Other Rebates, Discounts, or Other Price Concessions Associated With Sales of Drugs Provided to the Retail Pharmacy Class of Trade	No	Yes	No	Case-by-case

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ix Also includes 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. The Final Rule does not specifically address how to handle situations where contract pharmacy sales cannot be identified with adequate documentation as being subsequently resold to an excluded entity such as a LTC facility.

x Except to a PHS covered entity, an ICF/MR, or a State-owned or operated nursing facility.

xi When accepted or replaced in good faith, as described in the Final Rule.

xii Unless the price concessions are designed to adjust prices at the retail or provider level. Note that the term "provider" when used in this context includes MCOs. Therefore, if a rebate or other price concession to a PBM is designed to be passed through to an MCO, it *would* affect BP.

This chart is intended to serve as a summary of the guidance provided in the Final Rule. It is not an exhaustive summary, nor is it intended to address every factual scenario. Further, it is not intended in any way to serve as a substitute for legal advice or counsel. We encourage you to consult your legal adviser for counsel relating to the Final Rule and the interpretation thereof. Specific factual scenarios may result in a different outcome than set forth in this summary chart.

Retail Pharmacy Class of Trade

Section 1927(k)(1)(A) of the SSA defines AMP as "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,"[6] but does not define "wholesaler" or "retail pharmacy class of trade." CMS provides a definition of each of these terms in the Final Rule. The Final Rule defines "wholesaler" as "any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drugs, but that does not repackage or relabel the covered outpatient drugs."[7] This definition is similar to that previously contained in the CMS Medicaid Drug Rebate Agreement,[8] but differs from the definition in the Proposed Rule in that it does not include "pharmacy benefit managers" ("PBMs") or entities that "arrange for the sale of covered outpatient drugs."[9]

Further, the Final Rule defines "retail pharmacy class of trade" as "any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public."[10] Prior to this rulemaking, CMS had not defined the term "retail pharmacy class of trade," and the resulting ambiguity led to vast differences among pharmaceutical manufacturers in their AMP calculations. Notably missing from this new definition of "retail pharmacy class of trade" are PBMs and entities that "arrange for the purchase" of drugs. As with the definition of "wholesaler," although CMS proposed to include such entities in the definition of "retail pharmacy class of trade,"[11] the Final Rule excludes such entities except when they operate mail order pharmacies.

Authorized Generics

Section 6003 of the DRA amended Section 1927(b)(3)(A) of the SSA to require manufacturers of innovator drugs with authorized versions marketed under their New Drug Applications ("NDAs") to account for these "authorized generics" in their AMP and BP calculations.[12] The Final Rule defines "authorized generic" as "any drug sold, licensed, or marketed under an NDA . . . and marketed, sold, or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listing drug for use in institutions) than the brand drug."[13] Under the Final Rule, a "manufacturer holding title to the original NDA of the authorized generic drug must include the sales of this drug in its AMP only when such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler"[14] and must include in its BP calculations sales of the authorized generic drug "to any manufacturer, wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity in the United States, only when such drugs are being sold by the manufacturer holding title to the original NDA."[15] Thus, in a significant departure from the Proposed Rule, sales from the secondary manufacturer to its customers are not relevant to the primary (NDA-holding) drug manufacturer's AMP or BP calculations, thus "eliminat[ing] the need for manufacturers to share information on sales [with] other entities and potential competitors."[16] However, the transfer price that the primary manufacturer (the manufacturer holding the NDA) charges the secondary manufacturer (after deducting associated price concessions) must be included in the primary manufacturer's BP calculations; although, sales from the primary manufacturer to the secondary manufacturer are excluded from the primary manufacturer's AMP calculations.[17]

Bundled Sales

Under the Final Rule, manufacturers must apportion the aggregate discount resulting from a "bundled sale" between or among the drugs constituting the bundle in their AMP and BP calculations. The Final Rule defines "bundled sale" 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."[18] Notably, CMS leaves open the possibility that certain arrangements may be bundled at the NDC-11 (or package size) level.

Customary Prompt Pay Discounts

Section 6001(c) of the DRA amended Section 1927(k)(1) of the SSA to require that AMP be calculated without regard to customary prompt pay discounts.[19] The Final Rule defines "customary prompt pay discount" as "any discount off 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."[20] In the preamble to the Final Rule, CMS explains that such a discount is one that is "extended to all purchasers for payment within a set time period" and that discounts "that do not meet this standard which are used for other purposes (for example, marketing, sales, and promotional strategies, special package discounts, incentives, and performance based discounts) are not considered customary prompt pay discounts and should not be excluded from AMP."[21] Although the Final Rule does not address the issue specifically, it appears that customary prompt pay discounts to eligible entities must be treated as price concessions in BP calculations. There remains some ambiguity as to whether such discounts must be aggregated with downstream discounts for purposes of BP determinations.

Nominally Priced Sales

The Final Rule codifies the CMS Medicaid Drug Rebate Agreement definition of "nominal price," i.e., "a price that is less than ten percent of the AMP in the same quarter for which the AMP is computed."[22] Consistent with Section 1927(c)(1)(D) of the SSA, as amended by Section 6001(d)(2) of the DRA,[23] the Final Rule requires manufacturers to exclude nominally priced sales from their BP calculations if they are made to participants in the "Section 340B Drug Pricing Program" operated by the Health Resources and Services Administration, to intermediate care facilities for the mentally retarded ("IR-MRs"), or to state owned or operated nursing facilities.[24] The Final Rule now extends this exclusion to their AMP calculations.[25] All other nominally priced sales must be included in manufacturers' AMP and BP calculations, as appropriate, i.e., in AMP calculations if the sale is to an entity in the retail pharmacy class of trade[26] and in the BP calculations if the sale is to a BP-eligible entity.[27]

Administrative & Service Fees

Under the Final Rule, manufacturers must treat administrative and service fees as price concessions unless they meet the Rule's definition of "bona fide service fee,"[28] which the Final Rule defines as a fee "paid by a manufacturer to an entity; that represent[s] 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."[29] In the preamble to the Final Rule, CMS adopts the interpretive guidance that CMS provided in the final rule establishing the Medicare Part B physician fee schedule for CY 2007 relating to the definition of "bona fide service fee" for the purpose of calculating Average Sales Price ("ASP").[30] In the ASP final rule, CMS indicated that manufacturers should use "the most appropriate, industry-accepted method for determining fair market value of drug distribution services for which they contract."[31] With respect to whether a fee satisfies the "not passed on" prong of the definition, CMS has explained "[i]f a manufacturer has determined that a fee paid meets the other elements of the definition of 'bona fide service fee,' then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of an entity."[32]

Returned or Replaced Goods

The Final Rule requires manufacturers to exclude from their AMP calculations "[r]eturned or replaced goods when accepted or replaced in good faith."[33] In the preamble to the Final Rule, CMS explained that "returns made in good faith should be made in accordance with pre-existing manufacturer policies that comply with customary acceptable business practices; [sic] and applicable laws and regulations."[34] The Final Rule does not address how manufacturers should treat returned or replaced goods in their BP calculations.

Manufacturer Coupons & Vouchers

The Final Rule requires manufacturers to exclude from their AMP and BP calculations the value of manufacturer coupons that are "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."[35] The Final Rule also requires manufacturers to exclude from their AMP calculations the value of manufacturer vouchers.[36] Although the text of the Final Rule does not modify the term "voucher" in this AMP exclusion, the preamble to the Final Rule states: "vouchers for free sample products should be excluded from AMP in instances that the, voucher is not contingent on other purchase requirements and is redeemed by any entity other than the consumer, where the full value of the coupon is passed on to the consumer and the pharmacy does not receive any price concessions[]."[37] The Final Rule does not specifically address vouchers with respect to BP.

By contrast, the Proposed Rule did not address vouchers with respect to either the AMP or BP calculations, and proposed that manufacturers only exclude from their AMP and BP calculations the value of coupons redeemed by consumers directly to manufacturers.[38]

Base Date AMP

The "base date AMP" of a drug is generally the AMP for the first full quarter in which the drug is marketed.[39] The base date AMP is used to calculate whether a manufacturer must pay an additional inflationary-based rebate to the states. Because the Final Rule potentially changes several aspects of a manufacturer's AMP calculation, the additional rebate calculation may be disproportionately impacted. Therefore, the Final Rule permits, but does not require, manufacturers to recalculate base date AMPs on a product-by-product basis.[40] Revised base date AMPs must be calculated using data in "actual and verifiable pricing records"[41] and must be reported to CMS within the first four calendar quarters following publication of the Final Rule,[42] i.e., by September 30, 2008. Revised base date AMPs will apply prospectively from the quarter in which they are reported and may not be used to retrospectively adjust rebates, notwithstanding the fact that manufacturers have been instructed to calculate AMP without regard to prompt payment discounts since January 1, 2007.

Manufacturer Reporting & Recordkeeping Requirements

- **Monthly Reports**

Section 6001(b)(1)(A) of the DRA amended Section 1927(b)(3)(A) of the SSA to require manufacturers to report AMP on a monthly basis.[43] Pursuant to the Final Rule: "Monthly AMP should be calculated based on the best data available to the manufacturer at the time of the submission. In calculating monthly AMP, a manufacturer must estimate the impact of its lagged price concessions using a 12-month rolling average.[44] A lagged price concession means "any discount or rebate that is realized after the sale of the drug."[45] The Final Rule does not describe the exact

estimation methodology that manufacturers should use. Monthly AMP reports must be submitted to CMS within thirty (30) days of the last day of each month.[46]

- **Quarterly Reports**

Manufacturers must continue to report AMP and BP on a quarterly basis.[47] In a departure from the Proposed Rule, the Final Rule requires that quarterly AMPs be calculated as a weighted average of the AMPs for the three months comprising the quarter.[48] The Final Rule also requires manufacturers to report on a quarterly basis the aggregate value of all customary prompt pay discounts provided to wholesalers and of all nominally priced sales excluded from AMP and BP calculations.[49] Quarterly reports must be submitted to CMS within 30 days of the last day of each quarter.[50]

- **Certification**

Although not required by the SSA, the Final Rule requires that every report submitted to CMS be certified by the manufacturer's CEO or CFO (or an officer with equivalent authority) or by an "individual with the directly delegated authority to perform the certification on behalf of" such an officer.[51]

- **Restatements**

Existing regulations require manufacturers to restate quarterly AMPs and BPs that are subsequently determined not to have been accurate at the time they were submitted within 12 quarters of the original submissions.[52] The Final Rule extends this requirement to information concerning customary prompt pay discounts and nominally priced sales excluded from AMP and BP calculations.[53] Restatements of monthly AMPs must be submitted within thirty-six months of the month for which the AMP was calculated.[54] However, the Final Rule specifies that monthly and quarterly AMPs should not be restated if the revised value "would be solely as a result of data pertaining to lagged price concessions."[55]

- **Recordkeeping Requirements**

Existing regulations require manufacturers to retain records relating to calculations of quarterly AMPs and BPs for a period of at least 10 years.[56] The Final Rule extends this requirement to records relating to calculations of monthly AMPs and to customary prompt pay discounts and nominally priced sales excluded from AMP and BP calculations.[57]

Upper Payment Limits for Multiple Source Drugs

Section 6001(a) of the DRA amended Sections 1927(e)(4) and (5) of the SSA to require CMS to establish an FUL for any multiple source drug for which the U.S. Food and Drug Administration has rated at least two such drugs as therapeutically and pharmaceutically equivalent, provided that said drug is available from at least two suppliers.[58] Generally, the FUL for a multiple source drug is 250% of the AMP for the least costly therapeutic equivalent.[59] However, under the "outlier policy" described in the Final Rule, any AMP that is less than 60% of the next highest AMP will not be used to establish an FUL, unless the only multiple source drugs available are the innovator multiple source drug and the first noninnovator multiple source drug or authorized generic drug to enter the market.[60] With respect to this "outlier policy," CMS is soliciting additional public comments, which must be submitted within 180 days of publication of the Final Rule,[61] i.e., January 14, 2008.

Conditions for Federal Financial Participation in Payments for Physician-Administered Drugs

Under the Medicaid Drug Rebate Program, manufacturers are required to pay Medicaid rebates on drugs administered by physicians in the outpatient setting. In order to facilitate collection of these rebates, Section 6002 of the DRA amended Section 1927(a) of the SSA to require states, effective January 1, 2006, to require providers to include the NDCs for single source physician-administered drugs on claims submitted for payment.[62] Effective January 1, 2008, states also must require providers to include on their payment claims the NDCs for the twenty multiple source physician-administered drugs identified by CMS as the most costly to the Medicaid program in the aggregate.[63] States that do not comply with these requirements will not be entitled to federal contributory funds known as Federal Financial Participation with respect to the payments for these drugs.[64]

CONSIDERATIONS FOR MANUFACTURERS

We recommend that pharmaceutical manufacturers consider undertaking the following activities as they develop implementation plans relevant to the Final Rule:

- ✓ Update policies, procedures, job aids, process guides, manuals and other written standards to ensure adoption and implementation of a methodology that is consistent with the Final Rule including topics such as bundled discounts, prompt pay discounts, authorized generics and administrative and service fees.
- ✓ Review and reconfigure data management software and systems to reflect the written standards.
- ✓ Train all affected personnel, particularly those with responsibility for legal compliance, governmental pricing programs, trade departments, government affairs, and relationships with governmental and private health insurance programs (including MCOs).
- ✓ Reexamine class of trade and transaction classifications for AMP and BP calculations and revise accordingly.
- ✓ Reevaluate existing bundled discount arrangements and other discount agreements to ensure they are consistent with the Final Rule (and other health regulatory parameters).
- ✓ Establish process to estimate value of lagged price concessions based on 12-month rolling average.
- ✓ Create or update (and maintain) documentation of reasonable assumptions used in AMP and BP calculations.
- ✓ Identify customers receiving customary prompt pay discounts and ensure the creation and maintenance of adequate documentation of such determinations.
- ✓ Identify customers and transactions to be "excluded" from AMP, ensure adequate documentation (and maintenance thereof) regarding the classification of customers and transactions considered to be the non-retail pharmacy class of trade sales.
- ✓ Evaluate whether administrative, service and other fees qualify as "bona fide service fees" including analysis of Fair Market Value.

- ✓ Reevaluate authorized generic arrangements to assess the impact of the transfer prices on BP.
- ✓ Consider whether to revise and restate baseline AMPs, after assessing ability to do so.
- ✓ Consider submitting comments to CMS on the "outlier AMP" methodology that it will adopt in connection with establishing FULs for multiple source drugs.

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[1] 72 Fed. Reg. 39,142 (July 17, 2007). CMS released an advance copy of the Final Rule for public inspection on July 6, 2007 [hereinafter, "Adv. Copy" in citations]. When referencing the Final Rule in this Client Alert, we provide parallel citations to both the *Federal Register* and the advance copy.

[2] 42 U.S.C. § 1396r-8.

[3] 72 Fed. Reg. at 39,157 (Adv. Copy at 90).

[4] 71 Fed. Reg. 77,174 (Dec. 22, 2006).

[5] 72 Fed Reg. at 39,164 (Adv. Copy at 127).

[6] 42 U.S.C. § 1396r-8(k)(1)(A).

[7] 72 Fed. Reg. at 39,165 (Adv. Copy at 133); 72 Fed. Reg. at 39,241 (Adv. Copy at 564) (to be codified at 42 C.F.R. § 447.504(f)).

[8] *See* "Rebate Agreement Between the Secretary of Health and Human Services and the Manufacturer Identified in Section XI of this Agreement" ¶ I(ee) (hereinafter, "Rebate Agreement").

[9] *See* 71 Fed. Reg. at 77196.

[10] 72 Fed. Reg. at 39,164 (Adv. Copy at 130); 72 Fed. Reg. at 39,241 (Adv. Copy at 564) (to be codified at 42 C.F.R. § 447.504(e)).

[11] *See* 71 Fed. Reg. at 77,196.

[12] *See* 42 U.S.C. § 1396r-8(b)(3)(A).

[13] 72 Fed. Reg. at 39,243 (Adv. Copy at 575) (to be codified at 42 C.F.R. § 447.506(a)).

[14] *Id.* at 39,243 (Adv. Copy at 575) (to be codified at 42 C.F.R. § 447.506(b)).

[15] *Id.* at 39,243 (Adv. Copy at 576) (to be codified at 42 C.F.R. § 447.506(c)).

[16] *Id.* at 39,199-200 (Adv. Copy at 332); *compare* 71 Fed. Reg. at 77184.

[17] *See* 72 Fed. Reg. at 39,199-200 (Adv. Copy at 332).

[18] *Id.* at 39,240 (Adv. Copy at 557-58) (to be codified at 42 C.F.R. § 447.502).

[19] *See* 42 U.S.C. § 1396r-8(k)(1).

[20] 72 Fed. Reg. at 39,241 (Adv. Copy at 563-64) (to be codified at 42 C.F.R. § 447.504(c)).

[21] *Id.* at 39,166 (Adv. Copy at 140).

[22] *Id.* at 39,240 (Adv. Copy at 562) (to be codified at 42 C.F.R. § 447.502); Rebate Agreement, *supra* note 9, ¶ I(s).

[23] *See* 42 U.S.C. § 1396r-8(c)(1)(D). This section would also require manufacturers to exclude from their BP calculations prices to "[a]ny other facility or entity that [CMS] determines is a safety net provider based on the factors described in [Section 1927(c)(1)(D)(ii) of the SSA]," *id.* § 1396r-8(c)(1)(D)(i), but CMS declined to identify any such facility or entity in the Final Rule, *see* 72 Fed. Reg. at 39204 (Adv. Copy at 358-59).

[24] *See* 72 Fed. Reg. at 39,243 (Adv. Copy at 576) (to be codified at 42 C.F.R. § 447.508(a)).

[25] *See id.* at 39,241 (Adv. Copy at 565) (to be codified at 42 C.F.R. § 447.504(g)(4)); *see also id.* at 39,190 (Adv. Copy at 281).

[26] *See id.* at 39,241 (Adv. Copy at 565) (to be codified at 42 C.F.R. § 447.504(g)(4)).

[27] *Cf. id.* at 39,243 (Adv. Copy at 576) (to be codified at 42 C.F.R. § 447.508(a)).

[28] *Cf. id.* 39,242 (Adv. Copy at 569) (to be codified at 42 C.F.R. § 447.504(h)(19)); *id.* (Adv. Copy at 574) (to be codified at 42 C.F.R. § 447.505(d)(12)).

[29] *Id.* at 39,240 (Adv. Copy at 557) (to be codified at 42 C.F.R. § 447.502).

[30] *See id.* 39,182 (Adv. Copy at 231-33) (citing 71 Fed. Reg. 69,624, 69,668 (Dec. 1, 2006)).

[31] *See* 71 Fed. Reg. at 69,669.

[32] *See id.*

[33] 72 Fed. Reg. at 39,242 (Adv. Copy at 569) (to be codified at 42 C.F.R. § 447.504(h)(21)).

[34] *Id.* at 39,186 (Adv. Copy at 255).

[35] 72 Fed. Reg. at 39,242 (Adv. Copy at 568-69) (to be codified at 42 C.F.R. §§ 447.504(h)(15); *id.* (Adv. Copy at 573-74) (to be codified at 42 C.F.R. § 447.505(d)(8)).

[36] 72 Fed. Reg. at 39,242 (Adv. Copy at 569) (to be codified at 42 C.F.R. §§ 447.504(h)(16)).

[37] *See* 72 Fed. Reg. at 39,188 (Adv. Copy at 267-68).

[38] *See* 71 Fed. Reg. 77,197; *id.* at 77,198.

[39] *See* Rebate Agreement, *supra* note 9, ¶ I(c).

[40] *See* 72 Fed. Reg. at 39,243 (Adv. Copy at 578) (to be codified at 42 C.F.R. § 447.510(c)).

[41] *Id.*

[42] *See id.*

[43] *See* 42 U.S.C. § 1396r-8(b)(3)(A).

[44] *Id.* at 39,243 (Adv. Copy at 579) (to be codified at 42 C.F.R. § 447.510(d)(2)).

[45] 72 Fed. Reg. at 39,240 (Adv. Copy at 560) (to be codified at 42 C.F.R. § 447.502).

[46] 72 Fed. Reg. at 39,243 (Adv. Copy at 578) (to be codified at 42 C.F.R. § 447.510(d)(1)).

[47] *See id.* at 39,243 (Adv. Copy at 577) (to be codified at 42 C.F.R. § 447.510(a)).

[48] *See id.* at 39,242 (Adv. Copy at 570) (to be codified at 42 C.F.R. § 447.504(i)(2)); *compare* 71 Fed. Reg. at 77,197.

[49] *See* 72 Fed. Reg. at 39,243 (Adv. Copy at 577) (to be codified at 42 C.F.R. §§ 447.510(a)(1), (2)).

[50] *See id.* at 39,243 (Adv. Copy at 577) (to be codified at 42 C.F.R. §§ 447.510(a)(3), (4)).

[51] *See id.* at 39,243 (Adv. Copy at 579-80) (to be codified at 42 C.F.R. § 447.510(e)).

[52] *See* 42 C.F.R. § 447.534(i).

[53] *See* 72 Fed. Reg. at 39,243 (Adv. Copy at 577) (to be codified at 42 C.F.R. § 447.510(b)(1)).

[54] *See id.* (Adv. Copy at 579) (to be codified at 42 C.F.R. § 447.510(d)(3)).

[55] *See id.* (Adv. Copy at 577-78) (to be codified at 42 C.F.R. § 447.510(b)(2)).

[56] *See* 42 C.F.R. § 447.534(h).

[57] *See* 72 Fed. Reg. at 39,243 (Adv. Copy at 580) (to be codified at 42 C.F.R. § 447.510(f)(1)).

[58] *See* 42 U.S.C. § 1396r-8(e)(4); *see also* 72 Fed. Reg. at 39,244 (Adv. Copy at 582-83) (to be codified at 42 C.F.R. § 447.514(a)).

[59] *See* 42 U.S.C. § 1396r-8(e)(5); *see also* 72 Fed. Reg. at 39,244 (Adv. Copy at 583) (to be codified at 42 C.F.R. § 447.514(b)).

[60] *See* 72 Fed. Reg. at 39,244 (Adv. Copy at 583-84) (to be codified at 42 C.F.R. §§ 447.514(c)(2), (3)).

[61] *See id.*at 39,216-17 (Adv. Copy at 428).

[62] *See* 42 U.S.C. § 1396r-8(a)(7)(A); *see also* 72 Fed. Reg. at 39,244 (Adv. Copy at 586) (to be codified at 42 C.F.R. § 447.520(a)(1)).

[63] *See* 42 U.S.C. § 1396r-8(a)(7)(B); *see also* 72 Fed. Reg. at 39,244 (Adv. Copy at 586) (to be codified at 42 C.F.R. § 447.520(a)(2)).

[64] *See* 42 U.S.C. § 1396r-8(a)(7); *see also* 72 Fed. Reg. at 39,244 (Adv. Copy at 585-86) (to be codified at 42 C.F.R. § 447.520(a)).