

S. 1951 the “Fair Medicaid Drug Payment Act of 2007”

This bill was introduced August 2, 2007 by Senator Max Baucus, along with seven other Senators. It is designed to change the AMP formula and improve reimbursement to pharmacies for dispensing generic drugs under Medicaid. Provisions include:

- Remove mail order transactions and certain other discounts, rebates, and price concessions from calculation of AMP
- Base pharmacy payment on average AMP, instead of the lowest AMP
- Apply the AMP formula only when three or more alternatives are available, instead of two or more
- Raise Medicaid payment to 300% of AMP instead of 250%
- Require prior authorization for brand name drugs that are more expensive than³other biologically and therapeutically equivalent drug products²

Thanks to the following for their concise summaries on S.1951:

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APhA Summary

The Fair Medicaid Drug Payment Act of 2007

(S. 1951)

As Introduced August 2, 2007

Section 1. Short Title

Section 2. Providing Adequate Pharmacy Reimbursement under Medicaid

- Directs the Secretary of Health and Human Services (Secretary) to calculate the Federal upper reimbursement limit as no less than 300% of the weighted average (determined on the basis of utilization) of the most recent average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by community pharmacies on a nationwide basis.
- Directs the Secretary to implement a smoothing process for average manufacturer prices (AMP) to ensure that the Federal upper reimbursement limits do not vary

significantly from month to month as a result of rebates, discounts, and other pricing practices. Such process must be similar to the smoothing process used in determining the average sales price of a drug or biologic under section 1847A.

- Amends the current statutory definition of AMP as follows:
 - Average Manufacturer Price.

(A) In General. Subject to subparagraph (B), the term “average manufacturer price” means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States ~~by wholesalers for drugs distributed to the retail pharmacy class of trade~~ by-

(i) wholesalers for drugs distributed to retail community pharmacies; and

(ii) retail community pharmacies that purchase drugs directly from the manufacturer.

(B) ~~Exclusion of Customary Prompt Pay Discounts Extended to Wholesalers And Other Payments.~~ The average manufacturer price for a covered outpatient drug shall be determined ~~without regard to customary prompt pay discounts extended to wholesalers~~ regard to-

(i) customary prompt pay discounts extended to wholesalers;

(ii) bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);

(iii) reimbursement by manufacturers 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;

(iv) payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business primarily as a wholesaler or a retail community pharmacy;

(v) any payments made by manufacturers that are associated with drugs dispensed by retail community pharmacies;

(vi) any other discounts, rebates, payments, or other financial transactions that are not received by, paid by, or passed through to, retail community pharmacies.

(C) Inclusion of Section 505(c) Drugs. In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be

sold under a new drug application approved under section 505(c) of the Federal Food, Drug and Cosmetic Act, such term shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail pharmacy class of trade.

- Amends the statutory definition of multiple source drug as follows:
 - Multiple Source Drug. The term “multiple source drug” means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which ~~there is at least 1 other drug product~~ there are at least 2 other drug products which - ...
- Adds a definition of Retail Class of Pharmacy as follows:

Retail Community Pharmacy . The term “retail community pharmacy” means a traditional independent pharmacy , traditional chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by a State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.
- Adds a definition of Wholesaler as follows:

Wholesaler. The term “wholesaler” means a drug wholesaler that is licensed as a wholesaler by the State and that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) manufacturers, repackers, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer’s and distributor’s warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail pharmacies that conduct wholesale distributions.
- Amends current prior authorization programs as follows:

Requirements of Prior Authorization Programs. A State plan under this title may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval by the State of the use of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)). A State plan under this title shall, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, subject to prior authorization all covered outpatient drug products that are innovator multiple source drugs if such drug products are more expensive than other biologically and therapeutically equivalent drug products that are available for purchase in that State by retail community pharmacies. The system providing for such approval shall –

- (A) Require the prescriber to request prior authorization by substantiating the medical necessity of dispensing the covered outpatient drug as opposed to dispensing a substitute covered outpatient drug;
 - (B) Require that a prior authorization number assigned to the approved request by the State be included on the order for the covered outpatient drug issued by the prescriber or relayed to the dispensing pharmacist by the prescriber if the prescription is orally transmitted.
 - (C) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
 - (D) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).
- Amends current price disclosure requirements as follows:
 Manufacturer provision of price information.
 - (A) In General. Each manufacturer with an agreement in effect under this section shall report to the Secretary –
 - (i) not later than 30 days after the last day of each month of a rebate period under the agreement—
 - (I) on the average manufacturer price (as defined in subsection (k)(1)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and
 - (II) for single source drugs and innovator multiple source drugs (including all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), on the manufacturer’s best price (as defined in subsection (c)(1)(C)) for such drugs for the rebate period under the agreement;
 - (ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1)) as of October 1, 1990 for each of the manufacturer’s covered outpatient drugs (including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and
 - (iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size), and for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs.-
 - (I) the manufacturer’s average sales price (as defined in section 1847A(c)) and the total number of units specified under section 1847A(b)(2)(A);

- (II) if required to make payment under section 1847A, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and
- (III) information on those sales that were made at a nominal price or otherwise described in section 1847A(c)(2)(B); for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1842(o)(1) or section 1881(b)(13)(A)(ii).

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services.

Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs ~~and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v).~~

...

(D) Confidentiality of Information. Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except –

- (i) as the Secretary determines to be necessary to carry out this section,
- (ii) to permit the Comptroller General to review the information provided,
- (iii) to permit the Director of the Congressional Budget Office to review the information provided, and
- ~~(iv) to State to carry out this title, and~~
- ~~(v) to the Secretary to disclose (through a website accessible to the public) average manufacturer prices.~~

*Thank you APhA and others for breaking these bills down and sharing them with us!

*Thanks to Jim Smith, Executive Director of MPA, for making this information available to all of us!