

Appendix

**Proposed Changes to 42 C.F.R. §1001.952(h) (“Discounts”) and  
New Subsections 1001.952(c)(c) and (d)(d)**

Code of Federal Regulations  
Title 42 - Public Health  
Title: Section 1001.952 - Exceptions.

§ 1001.952 Exceptions.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

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(h) Discounts. As used in section 1128B of the Act, “remuneration” does not include a discount, as defined in paragraph (h)(5) of this section, on an item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs for a buyer as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section; a seller as long as the seller complies with the applicable standards of paragraph (h)(2) of this section; and an offeror of a discount who is not a seller under paragraph (h)(2) of this section so long as such offeror complies with the applicable standards of paragraph (h)(3) of this section.

(1) With respect to the following three categories of buyers, the buyer must comply with all of the applicable standards within one of the three following categories—

(i) If the buyer is an entity which is a health maintenance organization (HMO) or a competitive medical plan (CMP) acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, it need not report the discount except as otherwise may be required under the risk contract.

(ii) If the buyer is an entity which reports its costs on a cost report required by the Department or a State health care program, it must comply with all of the following four standards—

(A) The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;

(B) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;

(C) The buyer must fully and accurately report the discount in the applicable cost report; and

(D) the buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii) of this section, or information provided by the offeror as specified in paragraph (h)(3)(ii) of this section.

(iii) If the buyer is an individual or entity in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the buyer must comply with both of the following standards—

(A) The discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service; and

(B) the buyer (if submitting the claim) must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(iii)(B) of this section, or information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section.

(2) The seller is an individual or entity that supplies an item or service for which payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs to the buyer and who permits a discount to be taken off the buyer's purchase price. The seller must comply with all of the applicable standards within one of the following three categories—

(i) If the buyer is an entity which is an HMO a CMP acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, the seller need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is an entity that reports its costs on a cost report required by the Department or a State agency, the seller must comply with either of the following two standards—

(A) Where a discount is required to be reported to Medicare or a State health care program under paragraph (h)(1) of this section, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner that is

reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph; or

(B) Where the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; when the value of the discount becomes known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied; and refrain from doing anything which would impede the buyer from meeting its obligations under this paragraph.

(iii) If the buyer is an individual or entity not included in paragraph (h)(2)(i) or (h)(2)(ii) of this section, the seller must comply with either of the following two standards—

(A) Where the seller submits a claim or request for payment on behalf of the buyer and the item or service is separately claimed, the seller must provide, upon request by the Secretary or a State agency, information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section; or

(B) Where the buyer submits a claim, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.

(3) The offeror of a discount is an individual or entity who is not a seller under paragraph (h)(2) of this section, but promotes the purchase of an item or service by a buyer under paragraph (h)(1) of this section at a reduced price for which payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs. The offeror must comply with all of the applicable standards within the following three categories—

(i) If the buyer is an entity which is an HMO or a CMP acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, the offeror need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is an entity that reports its costs on a cost report required by the Department or a State agency, the offeror must comply with the following two standards—

(A) The offeror must inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such a discount and to provide information upon request under paragraph (h)(1) of this section; and

(B) The offeror of the discount must refrain from doing anything that would impede the buyer's ability to meet its obligations under this paragraph.

(iii) If the buyer is an individual or entity in whose name a request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the offeror must comply with the following two standards—

(A) The offeror must inform the individual or entity submitting the claim or request for payment in a manner reasonably calculated to give notice to the individual or entity of its obligations to report such a discount and to provide information upon request under paragraphs (h)(1) and (h)(2) of this section; and

(B) The offeror of the discount must refrain from doing anything that would impede the buyer's or seller's ability to meet its obligations under this paragraph.

(4) For purposes of this paragraph, a rebate is any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale.

(5) For purposes of this paragraph, the term discount means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction. The term discount does not include—

(i) Cash payment or cash equivalents (except that rebates as defined in paragraph (h)(4) of this section may be in the form of a check);

(ii) Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology

and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology;

(iii) A reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs;

(iv) A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary;

(v) Warranties;

(vi) Services provided in accordance with a personal or management services contract; ~~or~~

(vii) Other remuneration, in cash or in kind, not explicitly described in [this](#) paragraph (h)(5) ~~of this section;~~ [or](#)

[\(viii\) A reduction in price or other remuneration from a manufacturer in connection with the sale or purchase of a prescription pharmaceutical product to a plan sponsor under Medicare Part D, a Medicaid Managed Care Organization as defined in section 1903\(m\) of the Act, or to a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, or Medicaid Managed Care Organization, unless it is a price reduction or rebate that is required by law.](#)

[\(6\) For purposes of this paragraph \(h\), the term \*manufacturer\* carries the meaning ascribed to it in Social Security Act section 1927\(k\)\(5\).](#)

[\(7\) For purposes of this paragraph \(h\), the terms \*wholesaler\* and \*distributor\* are used interchangeably and carry the same meaning as the term “wholesaler” defined in Social Security Act section 1927\(k\)\(11\).](#)

(8) For purposes of this paragraph (h), the term *pharmacy benefit manager or PBM* means any entity that provides pharmacy benefits management on behalf of a health benefits plan that manages prescription drug coverage.

(9) For purposes of this paragraph (h), a *prescription pharmaceutical product* is either a drug or a biological as those terms are defined in Social Security Act section 1927(k)(2)(A), (B), and (C)

(10) For purposes of this paragraph (h), the term *Medicaid Managed Care Organization or Medicaid MCO* carries the meaning ascribed to it in section 1903(m) of the Social Security Act.

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(cc) *Point-of-sale reductions in price for prescription pharmaceutical products.*

(1) As used in section 1128B of the Act, “remuneration” does not include a reduction in the price charged by a manufacturer for a prescription pharmaceutical product that is payable, in whole or in part, by a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization, provided the manufacturer meets the following conditions with regard to that reduction in price:

(i) The reduced price must be set in advance with a plan sponsor under Medicare Part D, a Medicaid MCO, or the PBM acting under contract with either;

(ii) The sale does not involve a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback or series of chargebacks, or is required by law; and

(iii) The reduction in price must be completely applied to the price of the prescription pharmaceutical product charged to the beneficiary at the point of sale.

(2) *Definitions.*

(i) For purposes of this paragraph (cc), the terms *manufacturer, pharmacy benefit manager or PBM, prescription pharmaceutical product, rebate, and Medicaid managed care organization or Medicaid MCO* have the meanings ascribed to them in paragraph (h) of this section.

(ii) For purposes of this paragraph (cc), a *chargeback* is a payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment to the pharmacy for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between the Plan Sponsor under Part

D, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product.

(dd) PBM service fees. As used in section 1128B of the Act, “remuneration” does not include any payment by a pharmaceutical manufacturer to a pharmacy benefit manager (PBM) for services the PBM provides to the pharmaceutical manufacturer related to the pharmacy benefit management services that the PBM furnishes to one or more health plans as long as the following conditions are met:

(1) The PBM must have a written agreement with the pharmaceutical manufacturer that covers all of the services the PBM provides to the manufacturer in connection with the PBM’s arrangements with health plans for the term of the agreement and specifies each of the services to be provided by the PBM and the compensation associated with such services.

(2) The compensation paid to the PBM must:

(i) Be consistent with fair market value in an arm’s-length transaction;

(ii) Be a fixed payment, not based on a percentage of sales; and

(iii) Not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties, or between the manufacturer and the PBM’s health plans, for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

(3) The PBM must disclose in writing to each health plan with which it contracts at least annually, and to the Secretary upon request, the services rendered to each pharmaceutical manufacturer related to the PBM’s arrangements to furnish pharmacy benefit management services to the health plan.

(4) For purposes of safe harbor in this paragraph (dd), the terms *manufacturer*, *pharmacy benefit manager or PBM*, and *prescription pharmaceutical product* have the meanings ascribed to them in paragraph (h) of this section, and *health plan* has the meaning ascribed to it in paragraph (l) of this section.