(B) Has verified that a submitted NPI was not in fact active and valid; and
(C) The agreement between the parties explicitly permits such recoupment.

(v) With respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor’s acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.

(d) Treatment of compounded drug products. With respect to multi-ingredient compounds, a Part D sponsor must—

(1) Make a determination as to whether the compound is covered under Part D.

(i) A compound that contains at least one ingredient covered under Part B as prescribed and dispensed or administered is considered a Part B compound, regardless of whether other ingredients in the compound are covered under Part B as prescribed and dispensed or administered.

(ii) Only compounds that contain at least one ingredient that independently meets the definition of a Part D drug, and that do not meet the criteria under paragraph (d)(1)(i) of this section, may be covered under Part D. For purposes of this paragraph (d) these compounds are referred to as Part D compounds.

(iii) For a Part D compound to be considered on-formulary, all ingredients that independently meet the definition of a Part D drug must be considered on-formulary (even if the particular Part D drug would be considered off-formulary if it were provided separately—that is, not as part of the Part D compound).

(iv) For a Part D compound that is considered off-formulary—

(A) Transition rules apply such that all ingredients in the Part D compound that independently meet the definition of a Part D drug must become payable in the event of a transition fill under §423.120(b)(3); and

(B) All ingredients that independently meet the definition of a Part D drug must be covered if an exception under §423.578(b) is approved for coverage of the compound.

(2) Establish consistent rules for beneficiary payment liabilities for both ingredients of the Part D compound that independently meet the definition of a Part D drug and non-Part D ingredients.

(i) For low income subsidy beneficiaries the copayment amount is based on whether the most expensive ingredient that independently meets the definition of a Part D drug in the Part D compound is a generic or brand name drug (as described under §423.782).

(ii) For any non-Part D ingredient of the Part D compound (including drugs described under §423.104(f)(1)(i)(A)), the Part D sponsor’s contract with the pharmacy must prohibit balance billing the beneficiary for the cost of any such ingredients.

enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs as provided in paragraph (a) of this section to assume financial responsibility for any differential between the out-of-network pharmacy’s (or provider’s) usual and customary price and the Part D sponsor’s plan allowance, consistent with the requirements of §§423.104(d)(2)(I)(B) and 423.104(e).

(c) **Limits on out-of-network access to covered Part D.** A Part D sponsor must establish reasonable rules to appropriately limit out-of-network access to covered Part D drugs.

§ 423.128 Dissemination of Part D plan information.

(a) **Detailed description.** A Part D sponsor must disclose the information specified in paragraph (b) of this section in the manner specified by CMS—

(1) To each enrollee of a Part D plan offered by the Part D sponsor under this part;

(2) In a clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

(b) **Content of Part D plan description.** The Part D plan description must include the following information about the qualified prescription drug coverage offered under the Part D plan—

(1) **Service area.** The plan’s service area.

(2) **Benefits.** The benefits offered under the plan, including—

(i) Applicable conditions and limitations.

(ii) Premiums.

(iii) Cost-sharing (such as copayments, deductibles, and coinsurance), and cost-sharing for subsidy eligible individuals.

(iv) Any other conditions associated with receipt or use of benefits.

(3) **Cost-sharing.** A description of how a Part D eligible individual may obtain more information on cost-sharing requirements, including tiered or other copayment levels applicable to each drug (or class of drugs), in accordance with paragraph (d) of this section.

(4) **Formulary.** Information about the plan’s formulary, including—

(i) A list of drugs included on the plan’s formulary;

(ii) The manner in which the formulary (including any tiered formulary structure and utilization management procedures used) functions;

(iii) The process for obtaining an exception to a plan’s formulary or tiered cost-sharing structure; and

(iv) A description of how a Part D eligible individual may obtain additional information on the formulary, in accordance with paragraph (d) of this section.

(5) **Access.** The number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs and how the Part D sponsor meets the requirements of §423.120(a)(1) for access to covered Part D drugs;

(6) **Out-of-network coverage.** Provisions for access to covered Part D drugs at out-of-network pharmacies, consistent with §423.124(a).

(7) **Grievance, coverage determination, and appeal procedures.** All grievance, coverage determination, and appeal rights and procedures required under §423.562 et. seq., including—

(i) Access to a uniform model form used to request a coverage determination under §423.568 or §423.570, and a uniform model form used to request a redetermination under §423.582 or §423.584, to the extent such uniform model forms have been approved for use by CMS;

(ii) Immediate access to the coverage determination and redetermination processes via an Internet Web site; and

(iii) A system that transmits codes to network pharmacies so that the network pharmacy is notified to populate and/or provide a printed notice at the point-of-sale to an enrollee explaining how the enrollee can request a coverage determination by contacting the plan sponsor’s toll free customer service line or by accessing the plan sponsor’s Internet Web site.

(8) **Quality assurance policies and procedures.** A description of the quality assurance policies and procedures required under §423.153(c), as well as the