

plan or in a manner that may indicate diversion.

(7) State-level prescription drug monitoring program (PDMP) data.

(8) Geography, time, and distance between a prescriber and the patient.

(9) Refill frequency and factors associated with increased risk of opioid overdose.

*Insurance risk* means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

*Interchangeable biological product* means a product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that FDA has determined meets the standards described in section 351(k)(4) of the Public Health Service Act (42 U.S.C. 262(k)(4)), which in accordance with section 351(i)(3) of the Public Health Service Act (42 U.S.C. 262(i)(3)), may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

*Limited Income Newly Eligible Transition (LI NET) sponsor* means a Part D sponsor selected by CMS to administer the LI NET program.

*MA* stands for Medicare Advantage, which refers to the program authorized under Part C of title XVIII of the Act.

*MA plan* has the meaning given the term in § 422.2 of this chapter.

*MA-PD plan* means an MA plan that provides qualified prescription drug coverage.

*Medicare prescription drug account* means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

*Monthly beneficiary premium* means the amount calculated under § 423.286 for Part D plans other than fallback prescription drug plans, and § 423.867(a) for fallback prescription drug plans.

*MTM program* means a medication therapy management program described at § 423.153(d).

*PACE Plan* means a plan offered by a PACE organization.

*PACE organization* is defined in § 460.6 of this chapter.

*Parent organization* means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in a Part D sponsor or MA organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

*Part D eligible individual* means an individual who meets the requirements at § 423.30(a).

*Part D plan (or Medicare Part D plan)* means a prescription drug plan, an MA-PD plan, a PACE Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

*Part D plan sponsor or Part D sponsor* refers to a PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

*PDP region* means a prescription drug plan region as determined by CMS under § 423.112.

*PDP sponsor* means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans. This includes fallback entities.

*Pharmacist* means any individual who holds a current valid license to practice pharmacy in a State or territory of the United States or the District of Columbia.

*Prescription drug plan or PDP* means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of this part. This includes fallback prescription drug plans.

*Reference product* means a product as defined in section 351(i)(4) of the Public Health Service Act (42 U.S.C. 262(i)(4)).